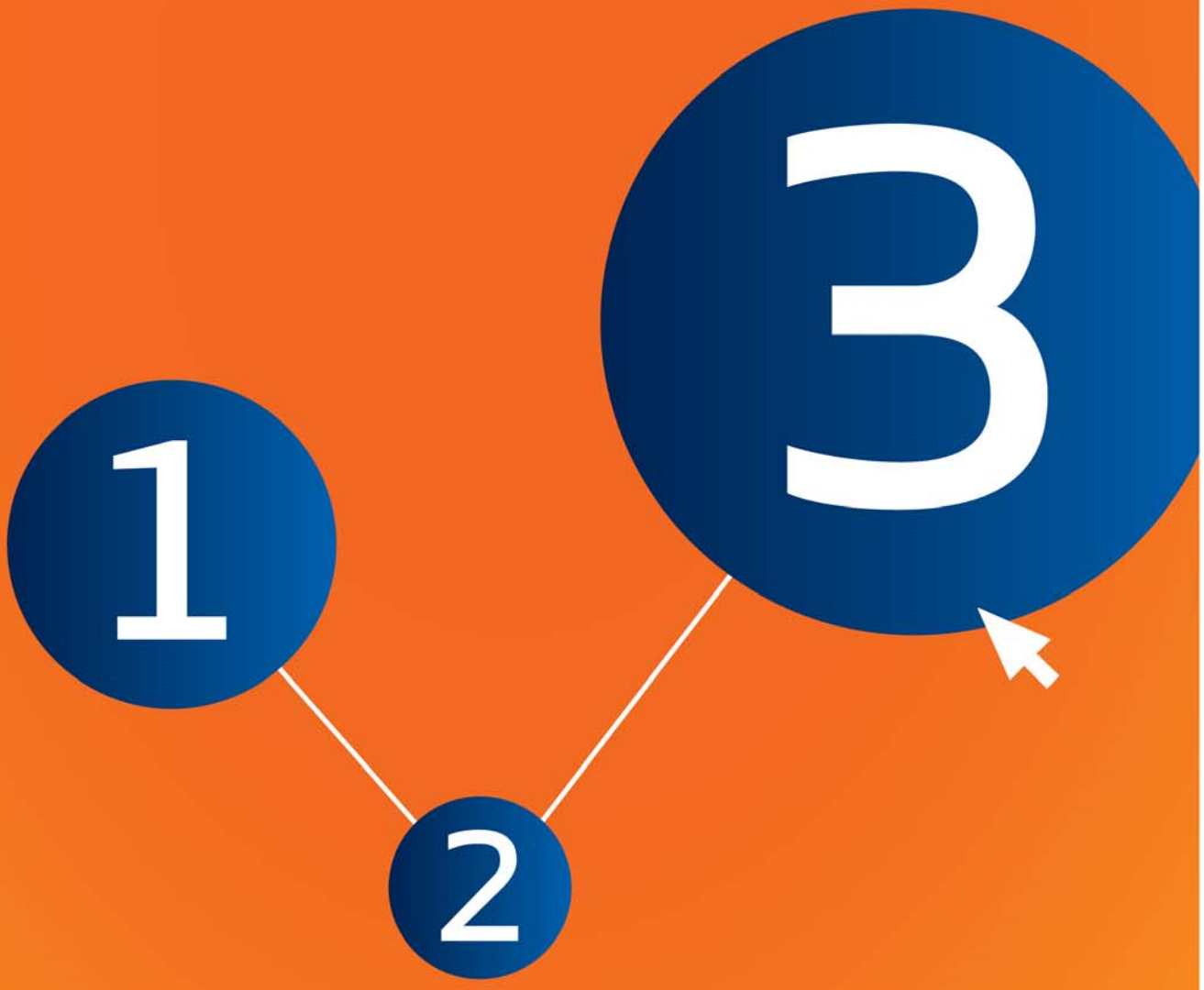
ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

Data Submission Manual

Part 04 - How to Pass Business Rule Verification ("Enforce Rules")



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Part 04 - How to Pass Business Rule Verification ("Enforce Rules")

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1. How to use this manual

Chapters 2 and 3 give a short overview of the steps required to ensure that a dossier passes Business Rules for submissions under the REACH Regulation 1907/2006. This three page summary contains the basic information that you need to know. In the appendices you will find detailed information relevant to your specific situations.

2. Introduction

The aim of this document is to help ensure that companies can successfully submit a dossier under the REACH Regulation 1907/2006 through REACH-IT, and in particular to explain the initial checks that are made by REACH-IT to determine whether the dossier can be accepted for further processing.

Dossier types currently undergoing these checks and described in this manual are:

- Registrations

This document outlines how and why these checks are carried out. It also aims to give guidance on how to prepare the substance dataset and the dossier header in order to be able to successfully pass the business rule verification.

One substance, one registration: REACH operates on the principle of one substance, one registration. If you have more than one substance to register then you need to make a series of single registrations. If you have a number of substances with similar structure and/or properties a category approach can be used but it is still necessary to submit a separate registration dossier for each substance being registered. More information on categories is provided in Section D6 and D8.2.5 of the IUCLID 5 end user manual.

Note that ECHA will develop and apply new business rules when required. Please check the web page regularly for updates.

2.1. Business Rule Verification

2.1.1. What are business rules?

All dossiers submitted to ECHA undergo administrative checks, called “business rules”. The business rules are a set of pre-requisites that must be fulfilled before ECHA can establish that the dossier can be handled properly and that the required regulatory processes can be successfully carried out. The business rules are checked using the REACH-IT software, and exist for two reasons:

- Format: In order to be processed correctly, REACH-IT must establish whether the dossier is in the correct IUCLID 5 format. For example, a PPORD notification must not be in the format of a registration dossier.
- Administrative: Before accepting a dossier for processing, ECHA must establish that it can be properly handled. This requires that certain administrative information has to be checked to ensure that it is consistent with the submission type. For example, if the dossier is an update following a regulatory request, but the reference number provided for the previous submission is incorrect, it would be impossible to establish a link with the previous dossier. Under other circumstances, it might be unclear how the dossier should be invoiced.

A dossier can be accepted for processing by ECHA only if all of the relevant business rules are satisfied. After that, the submission can proceed to the next steps (e.g. technical completeness

check (TCC) and invoicing). If the dossier submission fails at the business rule level, the dossier cannot be accepted for processing, and a new submission is required before any regulatory processes can be initiated.

2.1.2. Different types of business rules

The majority of business rules are checked automatically by REACH-IT. These are called 'Mandatory Business Rules'. However, once the Mandatory Business Rules have successfully passed, certain further Business Rules are carefully checked by ECHA staff. These are called 'Overrulable Business Rules'.

In case your dossier failed Mandatory Business Rules, you can see the results directly in your Submission Report. Overrulable Business Rule failures are sent to you by an official communication, available as a PDF in the 'Annotations' tab in your Submission Report.

For further details on how to access this information see Appendix 6.

2.1.3. Business rules versus TCC

The business rules check includes format validation and more specifically, includes a technical validation of information that is required for processing. This process is not part of the Technical Completeness Check as described in the REACH regulation.

2.1.4. Where can I find further information on dossier submission?

Further information on how to submit a notification or registration to ECHA is available on ECHA's website http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it. The information helps you to understand the topics covered and provides access to relevant documents, tools and web pages.

3. How to Pass Business Rules – IUCLID 5 preparations

This document is meant to be used as a "Business Rule Navigator", which will guide you through the basic steps of creating the substance dataset and the IUCLID dossier header. At the same time, it provides you with a basic understanding of Business Rule verification.

In essence there are four main steps to ensure that a dossier can pass the business rule verification. These are outlined in Figure 1 below.

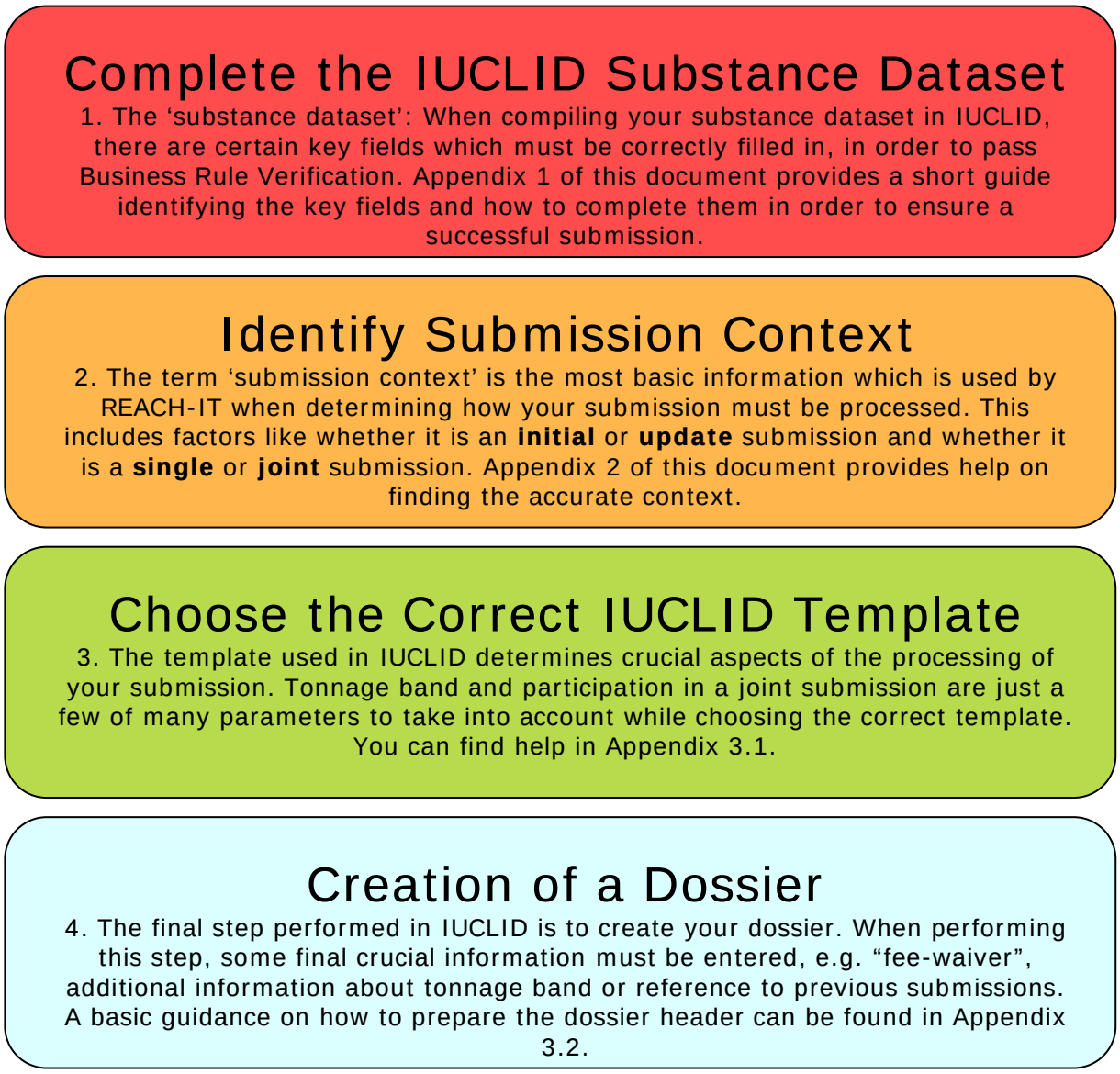
It is strongly recommended to use the Technical Completeness Check (TCC) tool on the substance dataset and then again, on the final version of your dossier. This IUCLID 5 plug-in will check completeness of your dossier but it also checks your dossier against most business rules before exporting it and submitting it to ECHA through REACH-IT.

To do that, right click on your substance dataset or dossier and select <Run TCC>.

You can download the latest version of the TCC plug-in from the IUCLID 5 website: http://iuclid.echa.europa.eu

Please note that as some of the business rules depend on information that is stored within the REACH-IT database, the plug-in cannot simulate all the business rules checked at ECHA. Furthermore, it is the submitter's responsibility to check the submission report – after submitting the dossier to REACH-IT – for potential business rule failures.

Figure 1: Four Steps of Passing Business Rule Verification


Complete the IUCLID Substance Dataset
1. The 'substance dataset': When compiling your substance dataset in IUCLID, there are certain key fields which must be correctly filled in, in order to pass Business Rule Verification. Appendix 1 of this document provides a short guide identifying the key fields and how to complete them in order to ensure a successful submission.
Identify Submission Context
2. The term 'submission context' is the most basic information which is used by REACH-IT when determining how your submission must be processed. This includes factors like whether it is an initial or update submission and whether it is a single or joint submission. Appendix 2 of this document provides help on finding the accurate context.
Choose the Correct IUCLID Template
3. The template used in IUCLID determines crucial aspects of the processing of your submission. Tonnage band and participation in a joint submission are just a few of many parameters to take into account while choosing the correct template. You can find help in Appendix 3.1.
Creation of a Dossier
4. The final step performed in IUCLID is to create your dossier. When performing this step, some final crucial information must be entered, e.g. "fee-waiver", additional information about tonnage band or reference to previous submissions. A basic guidance on how to prepare the dossier header can be found in Appendix 3.2.

For general guidance on dossier creation, refer to the IUCLID 5 User manual (http://iuclid.echa.europa.eu/index.php?fuseaction=home.documentation), section C.6 "Creating a dossier" and section D.8.2 "Creating dossiers".

Appendix 1 Complete the IUCLID Substance Dataset

The substance dataset contains a number of data fields which are crucial. Regardless of the type of submission, the information for these fields needs to be present.

In addition, given parts of the IUCLID file only have to be populated in specific cases. Below you can find the general information and guidance for the most crucial sections in IUCLID to be filled in for a successful business rule validation.

Appendix 1.1 Legal Entity in REACH-IT and in IUCLID Dossier

In the process of creating a dataset, creating a dossier and submitting it, there are three instances where the legal entity needs to be indicated. To avoid any ambiguity, you have to ensure that all these legal entities are the same.

- Section 1.1: The substance dataset is linked to a specific IUCLID legal entity. This must be the same as the REACH-IT legal entity from which the dossier will be submitted.

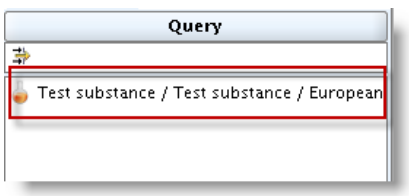
How to find the legal entity linked to the substance dataset?

- Click on “Substance” in the IUCLID main screen

Figure 2: IUCLID main screen - Substance

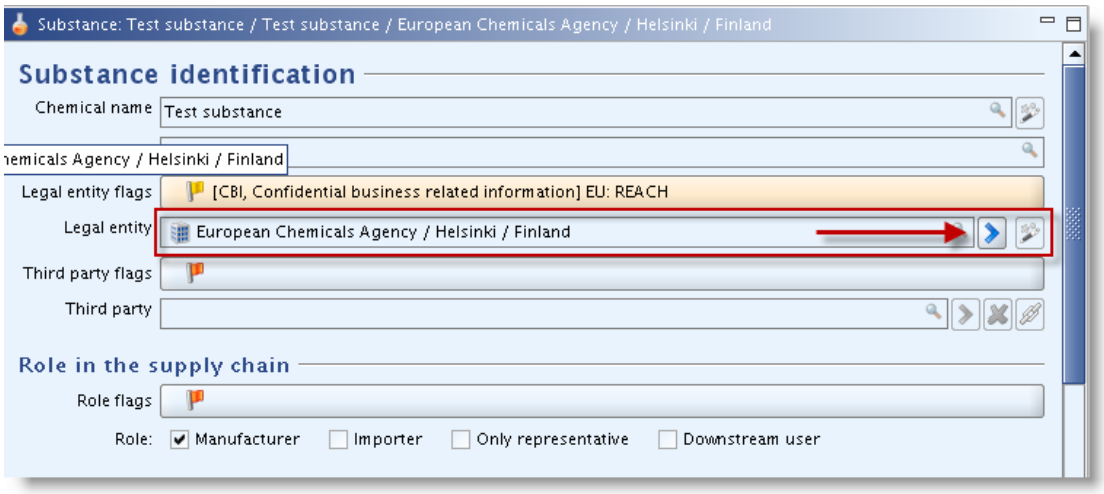
- Choose the substance in question from the query list

Figure 3: Query list - Substances



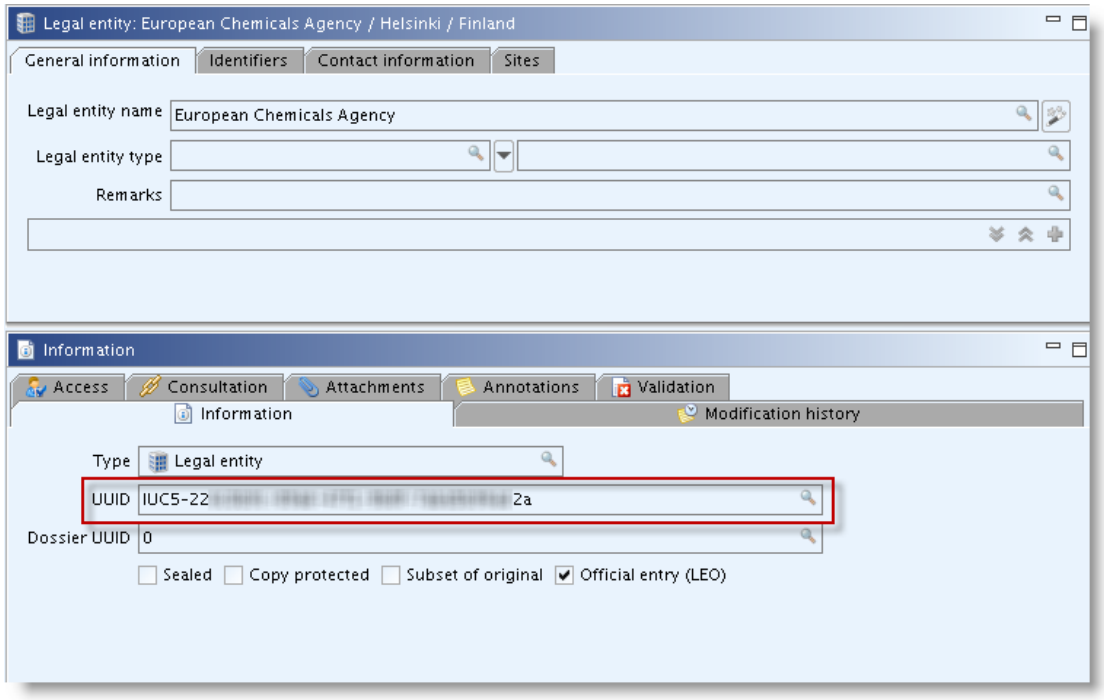
- Click on the blue arrow on the right end side of the “Legal entity” field

Figure 4: Section 1.1 - Substance identification



- In the "Information" field, under the "Information" tab, you can find the UUID of the legal entity associated with this substance.

Figure 5: The legal entity assigned to the reference substance

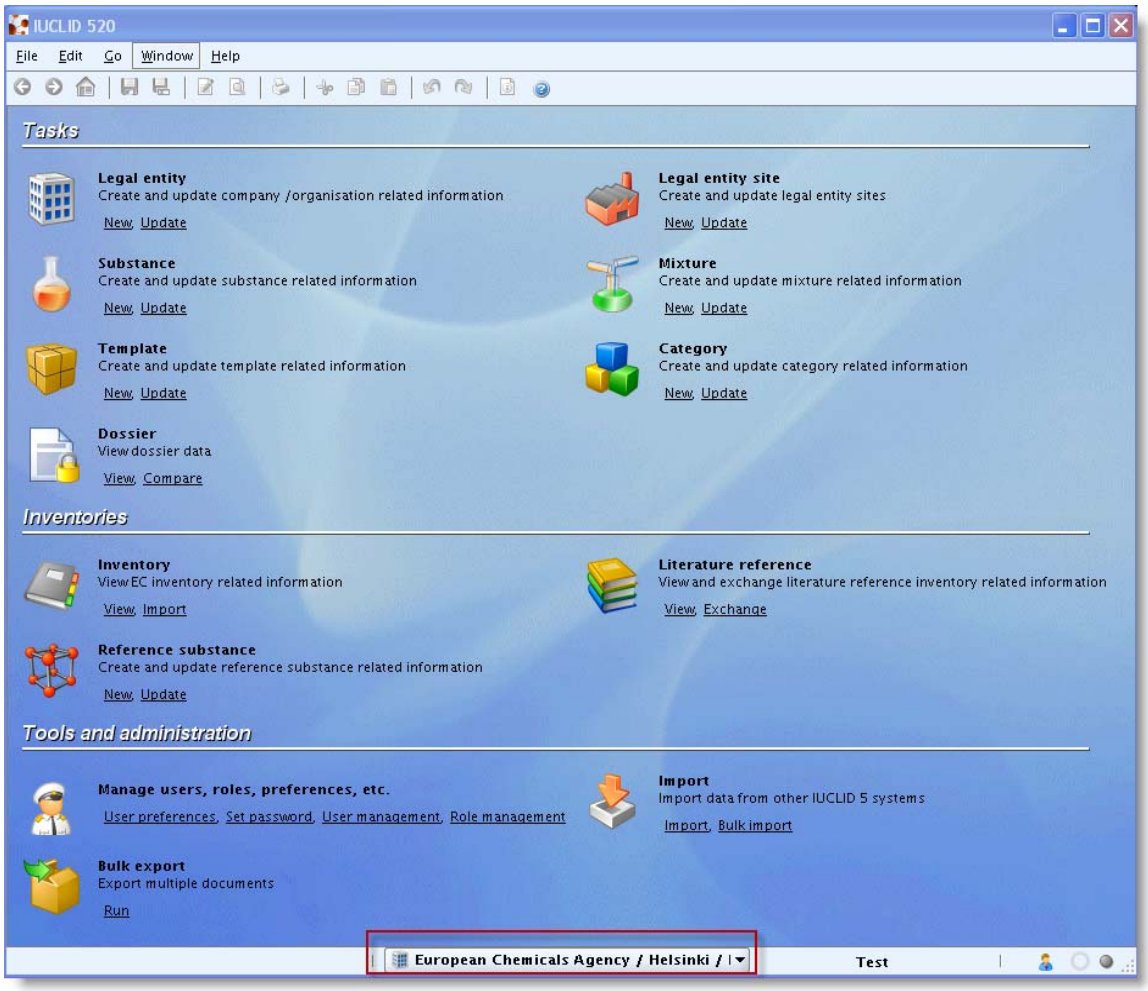


- Dossier Creation: When creating the dossier you must ensure that you use a IUCLID User Account for the legal entity which corresponds with the submitting legal entity in REACH-IT. This legal entity is visible at the bottom of IUCLID 5 screen, in the status bar.

How to find the legal entity that is "creating" the dossier?

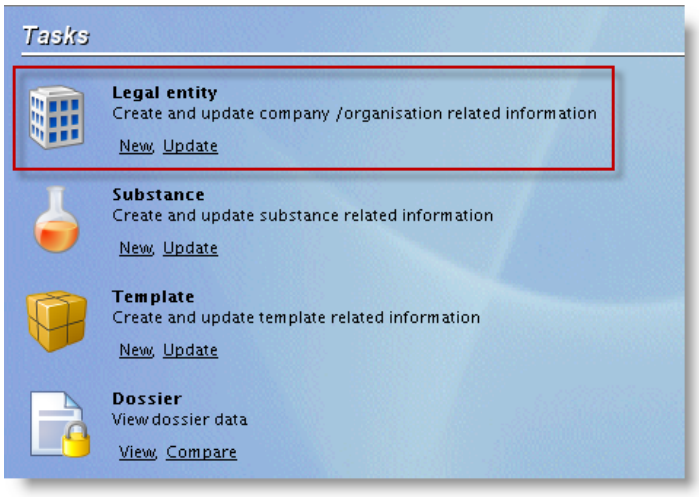
- On the bottom of the IUCLID main screen the selected legal entity is visible.

Figure 6: IUCLID main screen - Active legal entity



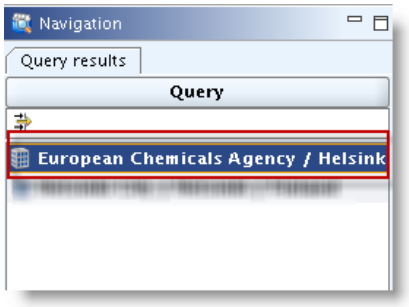
- Click on “Legal entity” on the IUCLID main screen

Figure 7: IUCLID main screen - Legal entity



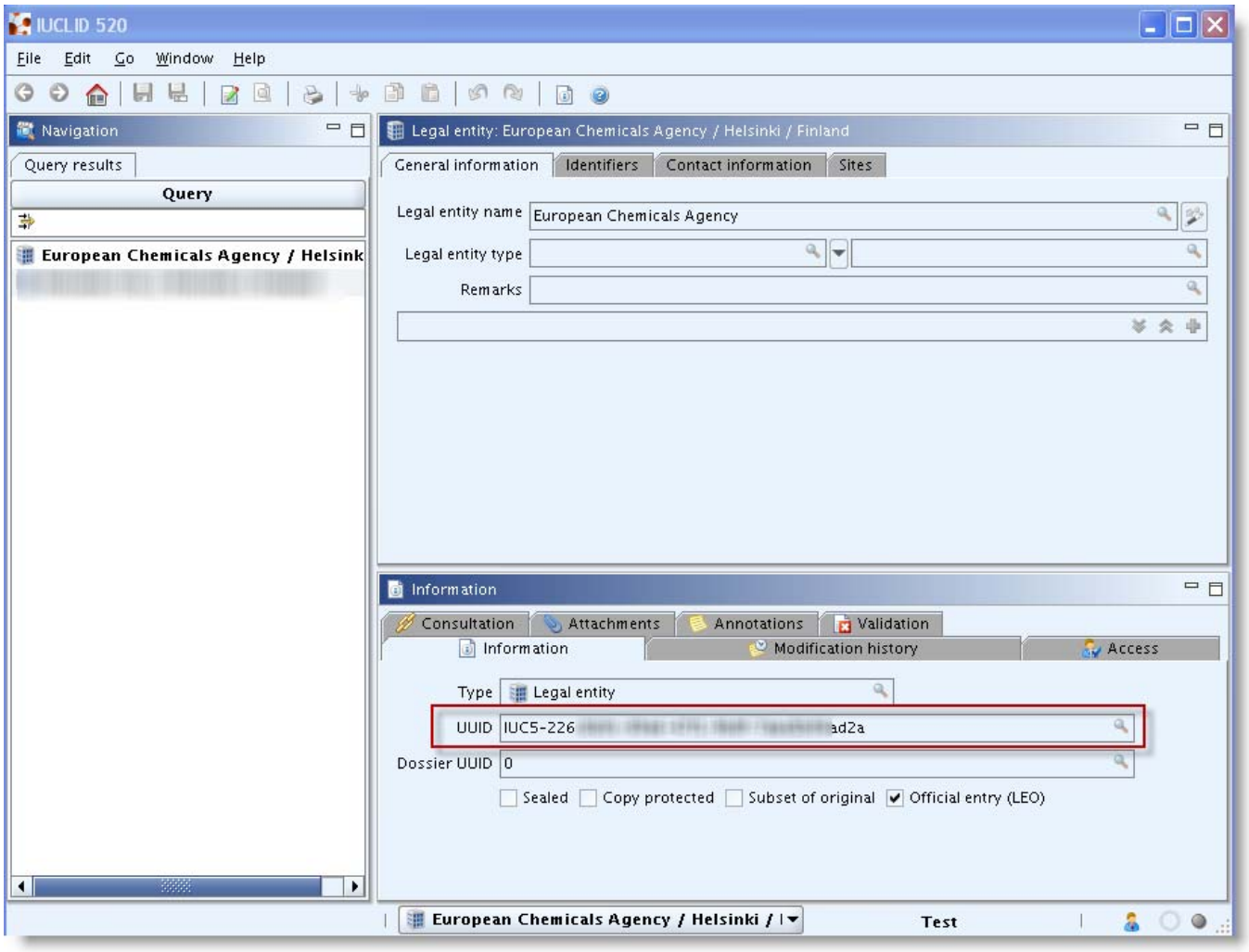
- Choose the same legal entity from the query list what you have seen at the bottom of the main screen previously.

Figure 8: Query list - Legal entities



- In the “Information” field, under the “Information” tab, you can find the UUID of the selected legal entity

Figure 9: Information about the legal entity creating the dossier



- REACH-IT: The account you use will determine the legal entity that ECHA will consider as associated with all the regulatory processes and/or communications concerning the submitted dossier.

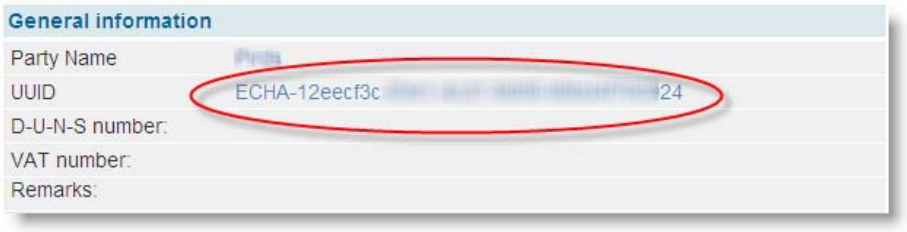
How to find the submitting legal entity in REACH-IT?

- Point to “Company” and click on “View”

Figure 10: REACH-IT main screen

- The second row in the "General information" field contains the UUID of the submitting legal entity

Figure 11: Information about the submitting legal entity in REACH-IT



If the three above mentioned legal entities are not the same, the submission will be rejected.

Please note that only official legal entity file used in IUCLID will be accepted for the purpose of dossier submission within the REACH-IT system. Official legal entity files (LEOX) are generated by REACH-IT or on the IUCLID website.

A legal entity created strictly within IUCLID 5 is not considered to be an official legal entity.

After the submission of the dossier, the REACH-IT system will compare the three above mentioned legal entities during the business rules verification step. The comparison is carried out on the UUIDs associated with the legal entities, not on their respective names.

Appendix 1.2 Section 1.1 – Identification

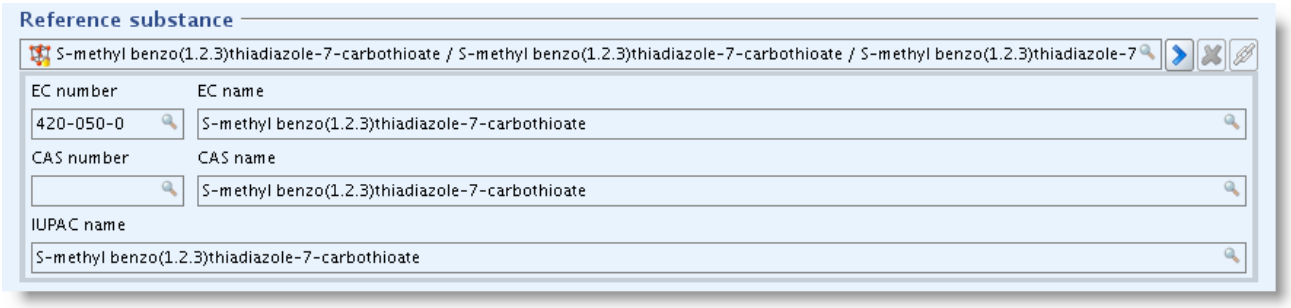
Section 1.1 in IUCLID is used for basic identification of both the substance and the submitting company.

If a Third party representative is included in the dossier, the company in question has to be already registered in REACH-IT as a "Third Party Representative".

The Reference Substance has to be identified with at least one of the following identifiers:

- EC Number
- CAS Number
- IUPAC Name – Please note that in order to be able to facilitate dissemination of information contained in the IUCLID dossier, a IUPAC name ALWAYS has to be present in section 1.1!

Figure 12: Example for identifying the reference substance



Absence of the EC Number assigned to the substance will lead to Business Rules failures in the following cases:

- The submission is an update
- The submission contains a valid Inquiry number in Section 1.3 (the EC number given in the inquiry result has to be in line with the one used in Section 1.1)

The following information has to be taken into account, when choosing the correct “Role in the supply chain”:

- If “Manufacturer” is selected, a production site in section 3.3 “Sites” must be provided. And it has to be linked to a “Manufacture” use in section 3.5.
- The role “Downstream user” cannot be selected if the submission only covers intermediates.
- If “Downstream user” is selected, at least one row in “Article service life” in section 3.5 must be filled in.
- The role “Only representative” cannot be selected together with “Manufacturer” or “Importer”.

For more information on Guidance for identification, please see Guidance for identification and naming of substances under REACH.

(Available at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation)

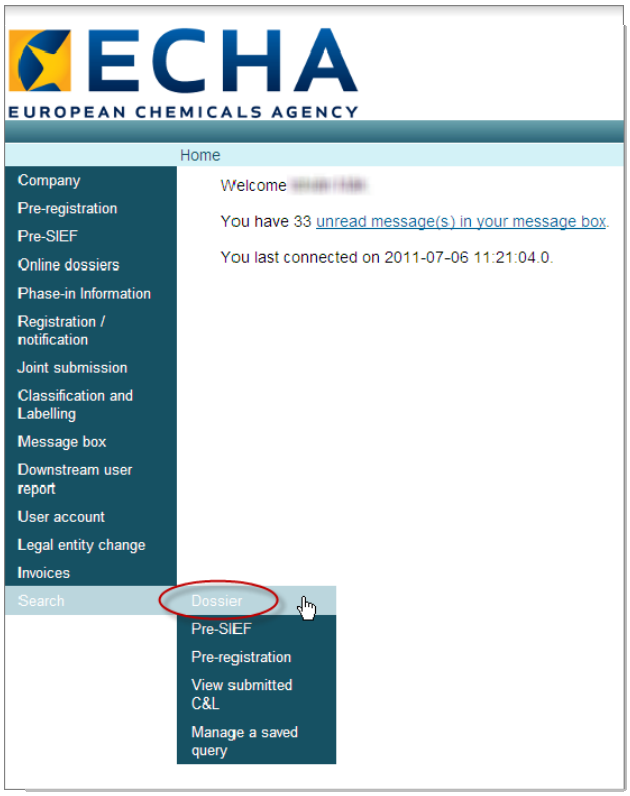
Appendix 1.2.1 Downloading the EC number from REACH-IT

In case you were unable to provide an EC number in your initial submission, REACH-IT will have automatically assigned one. **This number must be used** in any subsequent updates. These automatically created EC Inventory entries can be downloaded in i5z IUCLID 5 file format from REACH-IT.

To download the EC number, please follow the steps below:

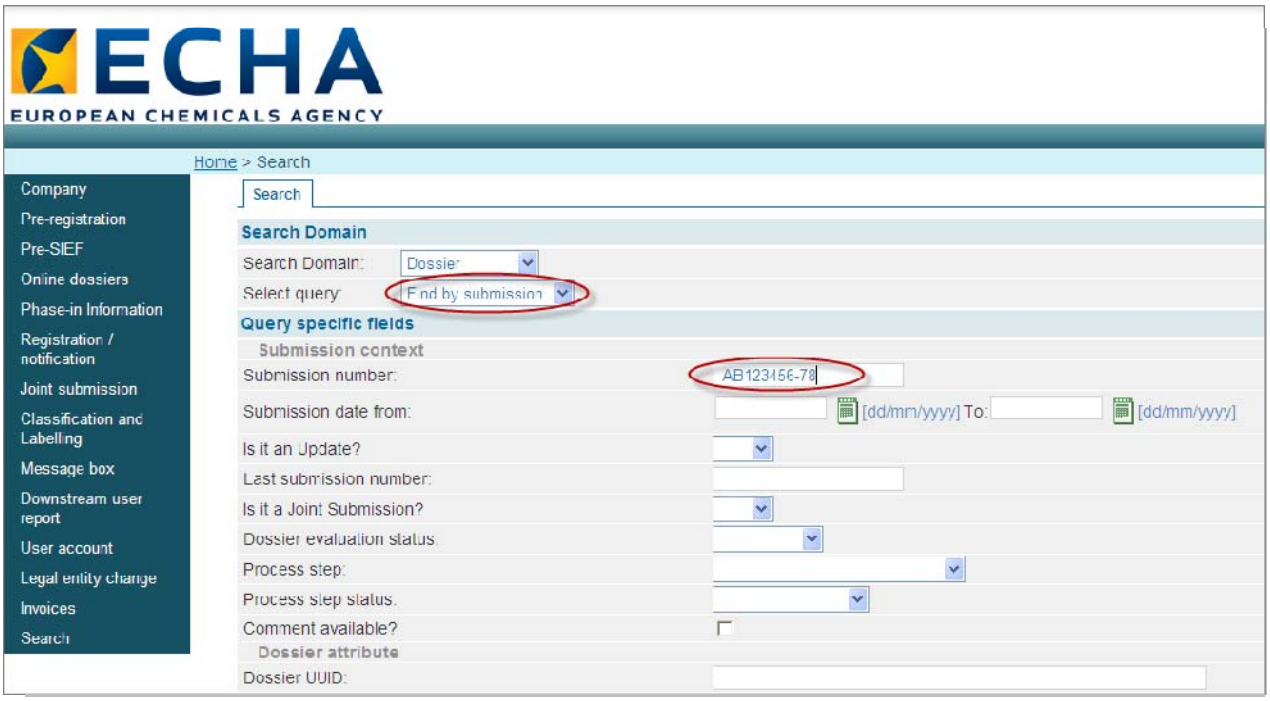
1. Log-in to REACH-IT and click on “Search” for “Dossier”.

Figure 13: REACH-IT Home Screen



2. From the query list select “Find by submission” and enter the submission number of the dossier you wish to update into the appropriate field.

Figure 14: Searching for Dossier in REACH-IT

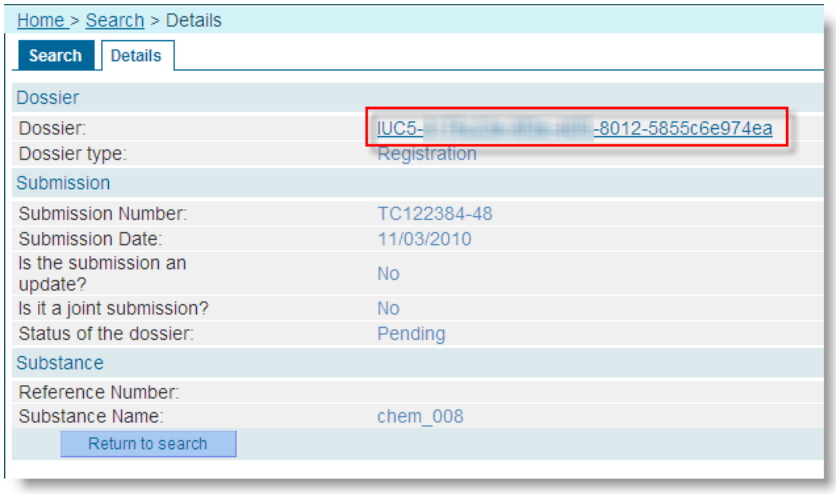


3. In the results field click on the UUID of the dossier.

Figure 15: Search Results in REACH-IT

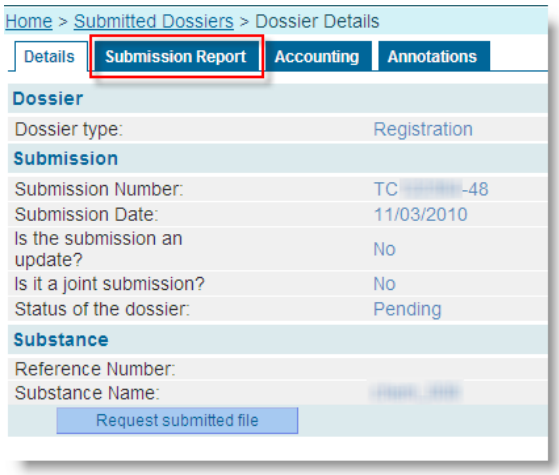
4. Click again on the Dossier's UUID in the new page.

Figure 16: Dossier Details



5. Choose the "Submission Report" tab.

Figure 17: Dossier Further Details



6. In the bottom of the Submission report you will find a button to export the EC Inventory Entry in IUCLID 5 format.

Figure 18: Exporting EC number from REACH-IT

7. Import the downloaded i5z file into your IUCLID installation and use it in your update dossiers.

Appendix 1.3 Section 1.2 – Composition

A Substance is defined by its composition. The composition of a Substance can consist of constituents, impurities and additives. This section is a repeatable block section.

The following information has to be included in this section:

- In Section 1.2 in all cases:
- There must be at least one composition with at least one constituent
  - Each constituent must have at least one identifier (EC number or CAS number or IUPAC name)
- Further requirements for Constituents:
  - For “mono constituent substance” there can only be one constituent included in Section 1.2 which has the same identity as given in Section 1.1
  - For “multi constituent substance” at least two constituents must be present. None of these constituents can be the same as the one used in Section 1.1. In exceptional cases, there can also be only one constituent present, but under these circumstances this constituent has to be the same as in Section 1.1.

If there are 2 or more compositions AND 2 or more classification and labelling block (in section 2.1) present, ALL the compositions must be linked to at least one classification and labelling block in section 2.1.

Appendix 1.4 Section 1.3 – Identifiers

Certain regulatory identifiers must be included in Section 1.3, as outlined below.

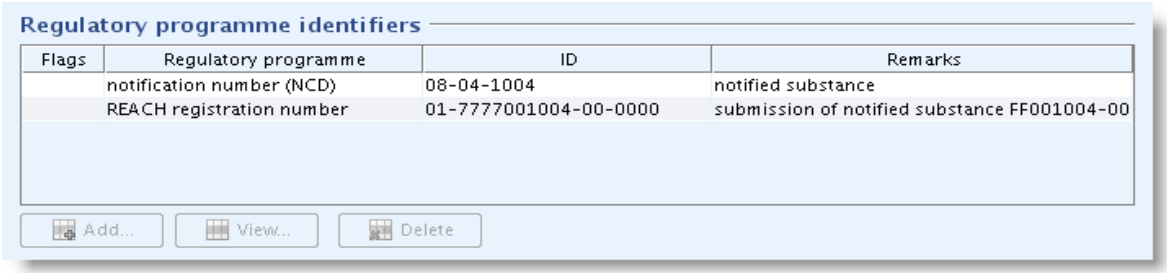
- REACH Registration Number: Registration numbers are obtained by successfully registering a substance or by claiming a notified substance. The provided number has to belong to the submitting company, and has to point to the reference substance used

in Section 1.1 of the dossier. In case you are updating an already registered substance please use the registration number you obtained when you submitted your dossier.

- Notification Number (NCD): If your registration number was granted by ECHA for a substance previously notified under Directive 67/548/EEC you must provide the Notification (NCD) Number in addition to the registration number. The dossier's submitting company has to match with the company who claimed the notification in REACH-IT. Also, the substance identity must be the same in the dossier and in the notification.
- REACH Pre-registration number: When provided (ie. when submitting a registration for a pre-registered phase-in substance), the indicated pre-registration number has to belong to the submitting company.
- REACH PPORD Notification Number: For PPORD notifications, the provided number has to belong to the submitting company, and has to point to the reference substance used in Section 1.1 of the dossier.
- REACH Inquiry Number: When provided (i.e. when submitting a registration following an inquiry) the number has to belong to the submitting company and the EC number which was provided by ECHA after this inquiry must match the one used in Section 1.1.
- REACH downstream user report number: When updating a Downstream user report, this number has to be included in the update dossier. The number has to be in the correct format, has to belong to the submitting legal entity and has to refer to the correct substance (i.e. same EC number)
- REACH substance in article notification number: When updating a Substance in article notification, this number has to be provided in the update dossier. The number has to be in the correct format, has to belong to the submitting legal entity and has to refer to the correct substance (i.e. same EC number)

Please note, that the downloadable TCC plug-in for IUCLID checks the format of the regulatory identifier, but as it is not connected the to REACH-IT database, it CAN NOT check the validity of these numbers.

Figure 19: Regulatory programme identifiers in Section 1.3



Appendix 1.5 Section 1.5 – Joint submission

The information of the Joint Submission is completely derived from REACH-IT (the joint submission name must be provided in REACH-IT while uploading the dossier) and any information in Section 1.5 is not taken into account. Section 1.5 can be used for your own administrative purposes, but it is important to note that the consistency of any information in this section of IUCLID will not be verified against the information derived from REACH-IT.

However, should you be submitting an individual dossier, this section has to be empty.

Appendix 1.6 Section 2.1 – GHS and Section 2.2 – DSD – DPD

In a registration dossier the classification and labelling information must be provided in Section 2. In case of a Joint Submission this information will be provided by the lead and is not expected to be in the member dossier, unless in the case Section 2 is part of the information for which an opt-out applies.

- Since 01/12/2010 the dossier must contain the classification and labelling information according to the GHS (Section 2.1) classification.

For more information on Classification and Labelling, please see Data Submission Manual 5 (available at http://echa.europa.eu/support/dossier-submission-tools)

Appendix 1.7 Section 2.3 PBT Assessment

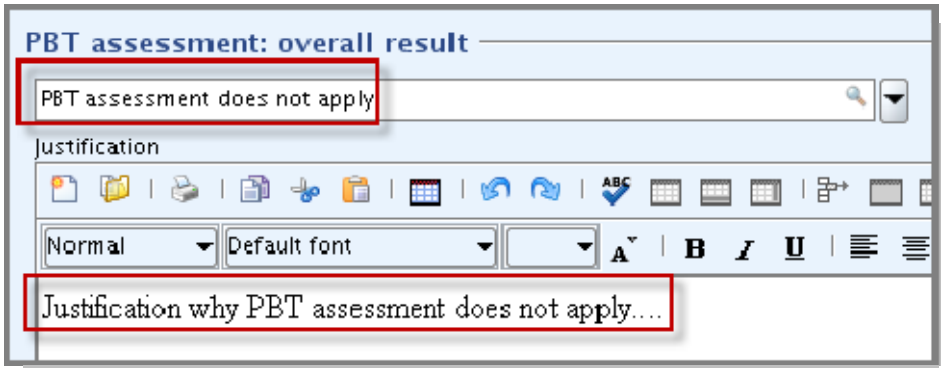
If a Chemical Safety Report (CSR) is required, the outcome of the PBT assessment must be provided.

CSR is required in the following cases:

- Individual dossier containing standard registration for above 10 t / year
- Member submissions for standard registrations for above 10 t/ year
- Lead submissions for standard registrations for above 10 t/ year
- Lead submissions regardless of the registered tonnage band, in case they declare that they are providing the CSR on behalf of their members

In case registrant selects “PBT assessment does not apply” from the drop-down list, a justification must be provided to explain this situation (Figure 20).

Figure 20: PBT Assessment not required



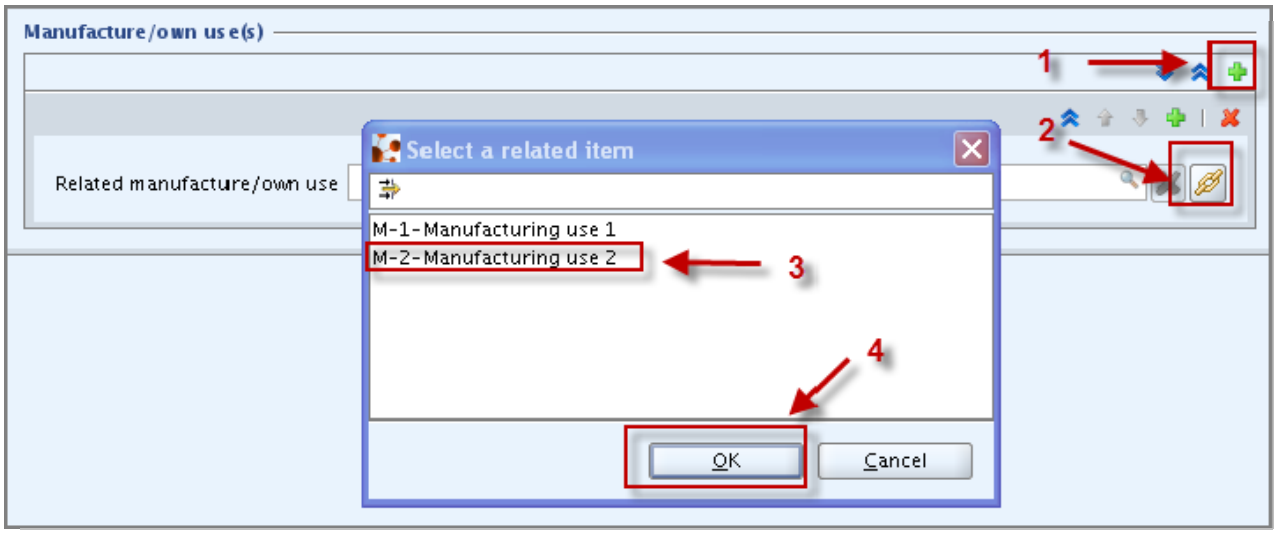
Appendix 1.8 Section 3.3 – Sites

This section is a repeatable block section, which offers the possibility to list all sites where the Substance is produced and/or used. This is done by creating for each site a link with the relevant information stored in the Legal entity site inventory. The minimum data required is

town / city and the country, where the site is located. Please note that in the case of an importer no information is required in this section, however, if a site is provided, the same requirement applies.

If “Manufacturer” is selected in Section 1.1 “Role in the supply chain”, then at least one site has to be linked to a “Manufacture” use from Section 3.5. To do this, click on the small green cross at the “Manufacture / own use(s)” section of a site and link a manufacturing use after clicking on the small “golden chain” (Figure 21).

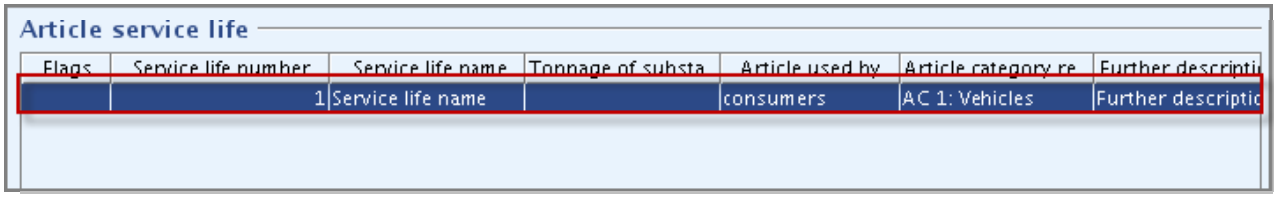
Figure 21: Linking Manufacturing use to a site



Appendix 1.9 Section 3.5 – Life Cycle description

If “Downstream user” is selected in Section 1.1 “Role in the supply chain”, then at least one “use” has to be present in “Article service life” in Section 3.5 “Life Cycle description” of IUCLID (Figure 22).

Figure 22: Article service life



Appendix 2 Identify Submission Context

The submission context is the regulatory context in which you make the submission. An example could be the “initial submission of a 1-10 tpa dossier as a member of a Joint Submission”. This context defines which information must be available in the dossier to enable it to be processed.

The main factors in identifying the submission context is if the submission is a “Single Submission” or “Joint Submission”, or initial or update. In case of a joint submission, there are further options, as the dossier can be a “Lead” or a “Member”. A submission can be:

- Initial: no Registration number has been assigned to the submitting company for this substance.

- Spontaneous Update: the substance has already been successfully registered, but an update is needed. Possible reasons for the update can be found in Appendix 5.3.3.2.
- Requested Update: a submission has failed Technical Completeness Check, or after successful registration further information was requested (e.g. compliance check).

After identifying your submission, you can follow the links to the specific annexes, where you'll find examples of how your dossier header should look like, together with a checklist of special issues you have to take care of.

	Single Submission	**Joint Submission Lead**	**Joint Submission Member**
Initial	Appendix 4.1	Appendix 4.4	Appendix 4.7
Spontaneous Update	Appendix 4.2	Appendix 4.5	Appendix 4.8
Requested Update	Appendix 4.3	Appendix 4.6	Appendix 4.9

Appendix 3 Creating the dossier

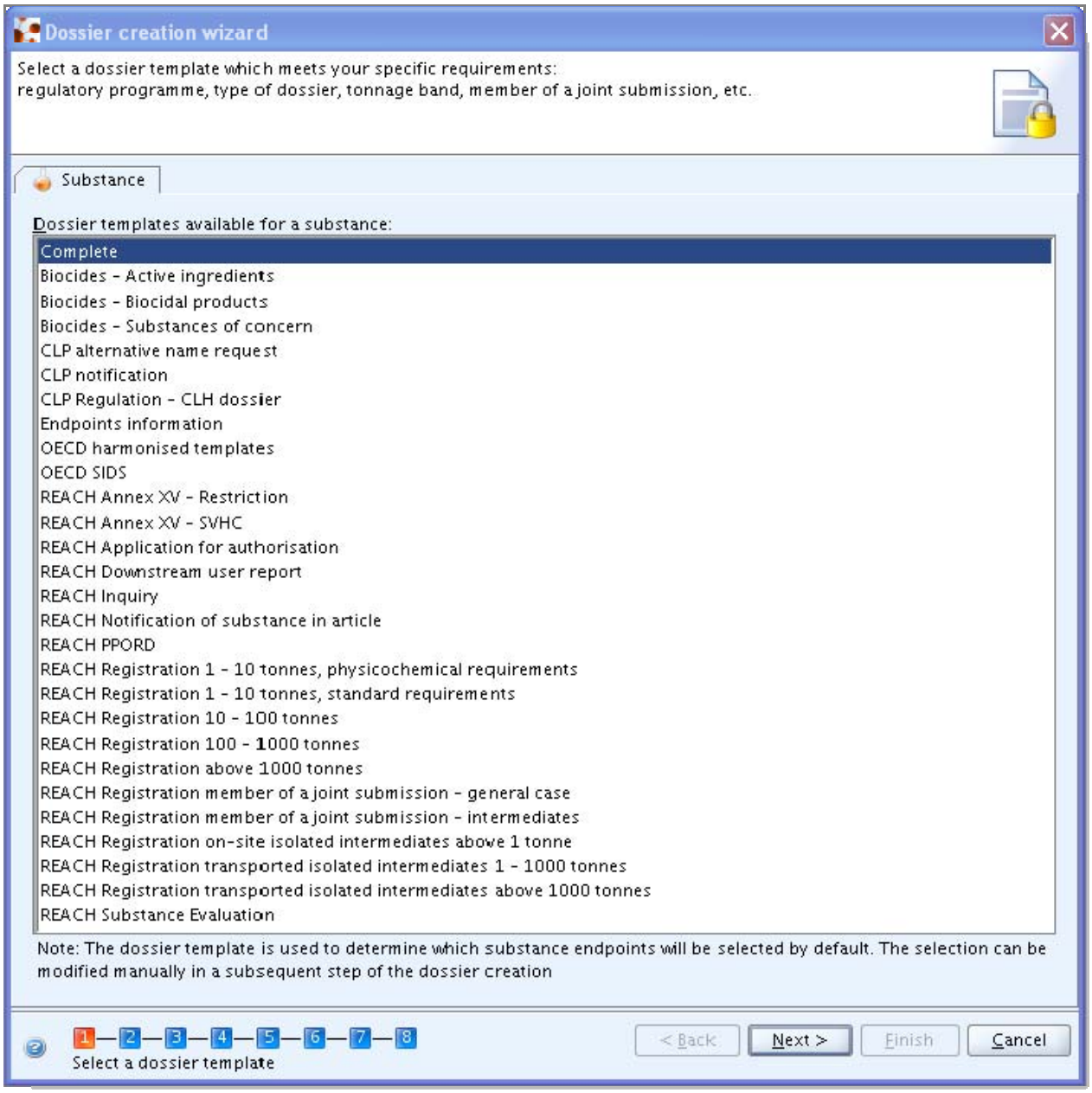
Appendix 3.1 Choosing the correct IUCLID 5 template

Choosing the correct dossier template is an important step in a successful submission, as the template indicates the tonnage band of the submission and determines amongst many other things which substance endpoints will be selected by default to export into your dossier.

Before exporting the data you have to make sure that the template selected corresponds with the intended submission (e.g. correct dossier type (Inquiry, PPORD, Registration, etc.) correct tonnage band). Note that in the case of a lead dossier in a Joint Submission, additional information about tonnage band has to be provided, more information about that can be found in Appendix 5.2.

Please note there is no specific template available for "lead" of Joint Submission, as for those cases the generic registration (both general and intermediate) and classification & labelling templates should be used. The information about the joint submission has to be indicated in those cases in the dossier header (Appendix 5.2).

Figure 23: Dossier Template Selection in IUCLID


Dossier creation wizard
Select a dossier template which meets your specific requirements:
regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.
Substance
Dossier templates available for a substance:
Complete
Biocides - Active ingredients
Biocides - Biocidal products
Biocides - Substances of concern
CLP alternative name request
CLP notification
CLP Regulation - CLH dossier
Endpoints information
OECD harmonised templates
OECD SIDS
REACH Annex XV - Restriction
REACH Annex XV - SVHC
REACH Application for authorisation
REACH Downstream user report
REACH Inquiry
REACH Notification of substance in article
REACH PPORD
REACH Registration 1 - 10 tonnes, physicochemical requirements
REACH Registration 1 - 10 tonnes, standard requirements
REACH Registration 10 - 100 tonnes
REACH Registration 100 - 1000 tonnes
REACH Registration above 1000 tonnes
REACH Registration member of a joint submission - general case
REACH Registration member of a joint submission - intermediates
REACH Registration on-site isolated intermediates above 1 tonne
REACH Registration transported isolated intermediates 1 - 1000 tonnes
REACH Registration transported isolated intermediates above 1000 tonnes
REACH Substance Evaluation
Note: The dossier template is used to determine which substance endpoints will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation
1 2 3 4 5 6 7 8
Select a dossier template
< Back
Next >
Finish
Cancel

Individual submission dossier or Lead dossier		
Context	IUCLID 5 Template	Dossier type in REACH-IT
Standard Registration	Registration template with the corresponding tonnage band (e.g. REACH Registration 10-100 tonnes)	Registration
Standard Registration + Intermediate(s)	Registration template with the corresponding tonnage band (e.g. REACH Registration 10-100 tonnes)	Registration

Registration of one type of intermediate (i.e. On-Site OR Transported)	Intermediate template with the corresponding type and tonnage band (e.g. REACH Registration On-Site Isolated Intermediates above 1 tonne)	Registration of transported isolated intermediate or Registration of on-site isolated intermediate
Combination of Intermediates (i.e. On-Site + Transported Isolated Intermediates)	Transported Isolated Intermediate template with the corresponding tonnage band (e.g. REACH Registration transported isolated intermediates 1-1000 tonnes)	Registration of transported isolated intermediate
Member dossier		
Context	IUCLID 5 Template	Dossier type in REACH-IT
Standard Registration	REACH Registration member of a joint submission – general case	Registration
Standard Registration + Intermediate(s)	REACH Registration member of a joint submission – general case	Registration
Registration of one type of intermediate (i.e. On-Site OR Transported)	REACH Registration member of a joint submission – intermediates	Registration of transported isolated intermediate or Registration of on-site isolated intermediate
Combination of Intermediates	REACH Registration member of a joint submission – Intermediates	Registration of transported isolated intermediate

Appendix 3.2 Creation of a Dossier from a substance dataset

Dossier header: The dossier header is derived from information entered when creating the dossier. It consists of information used for administrative purposes and is completed by the applicant when preparing his dossier from the substance data set.

The information contained in the dossier header is crucial for Business Rules checking when you submit your dossier. Missing or incorrect information can result in the dossier not being accepted for further processing. For example, it might be unclear whether the dossier is intended as an update of a previous registration due to a tonnage band increase, or an update due to a request for further information after a first completeness check under Article 20 of REACH.

Because it is critical that ECHA clearly understands both the type of dossier and the specific circumstances behind the submission, REACH-IT will not process the dossier if this information

is unclear and/or incorrect.

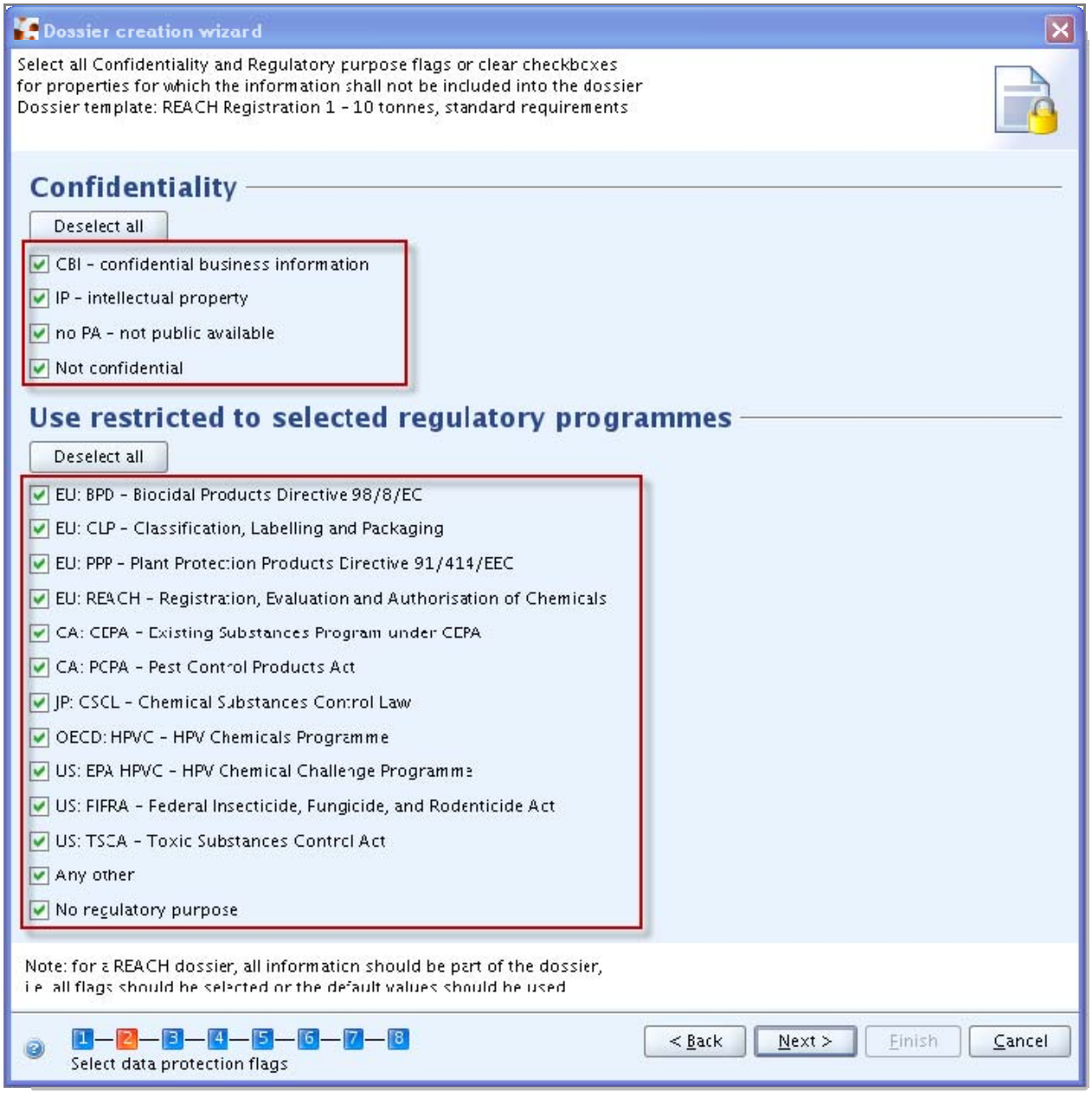
Appendix 3.3 Filtering the information to be included in the dossier

Most information entered into a IUCLID substance dataset can be flagged to be used specifically for the purpose of certain regulatory programmes. Furthermore, flags indicating request for confidentiality claim can also be introduced for these information.

If any of the fields within the substance dataset are “flagged” – let it be for confidentiality claim or for marking it for separate regulatory programmes – if that category is not specifically indicated to be included in the dossier (Figure 24), the information will not be exported into the newly created dossier.

For most cases ECHA would recommend you to select all the checkboxes, making sure that all required elements of the substance dataset are used.

Figure 24: Filtering information during the dossier creation process

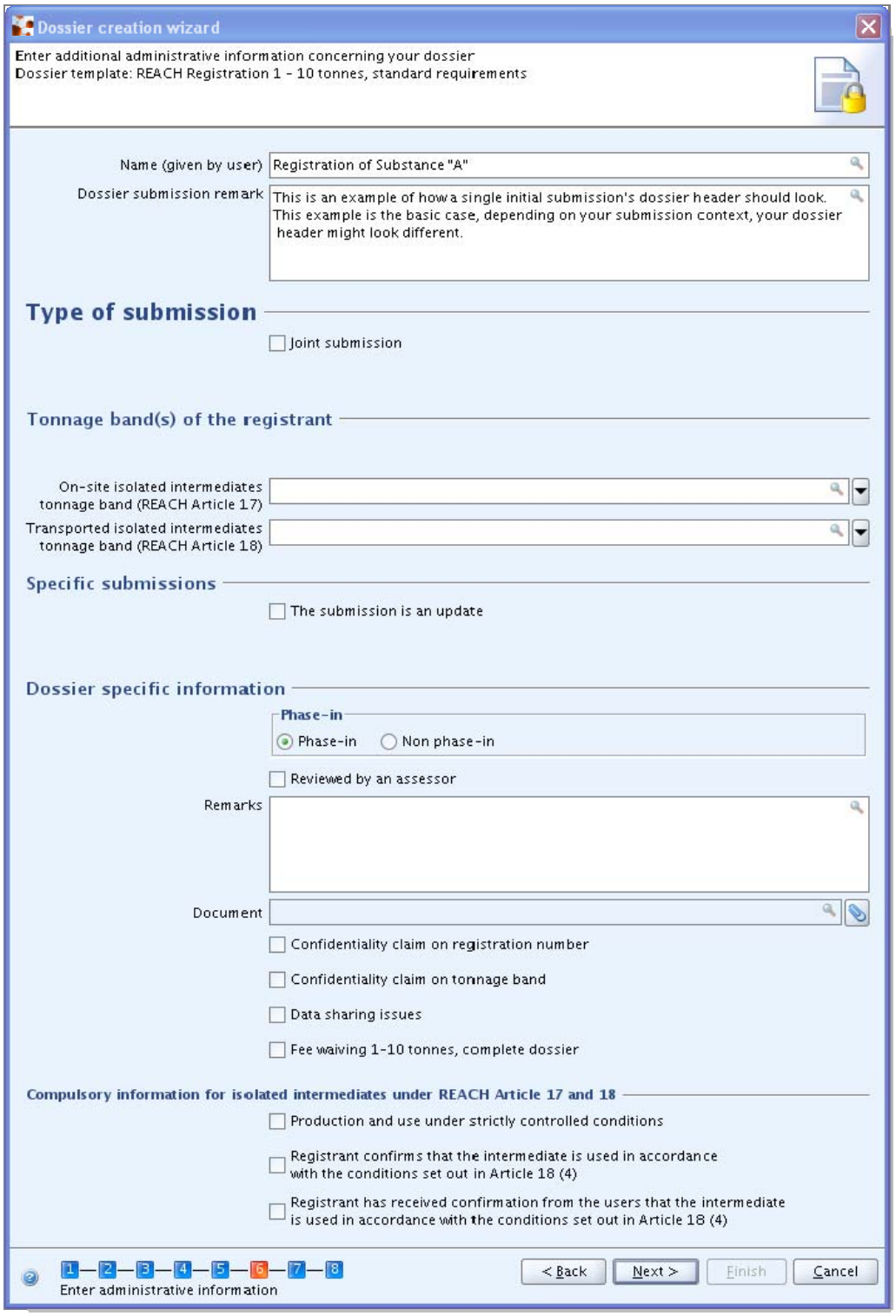

Dossier creation wizard
Select all Confidentiality and Regulatory purpose flags or clear checkboxes
for properties for which the information shall not be included into the dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Confidentiality
Deselect all
CBI - confidential business information
IP - intellectual property
no PA - not public available
Not confidential
Use restricted to selected regulatory programmes
Deselect all
EU: BPD - Biocidal Products Directive 98/8/EC
EU: CLP - Classification, Labelling and Packaging
EU: PPP - Plant Protection Products Directive 91/414/EEC
EU: REACH - Registration, Evaluation and Authorisation of Chemicals
CA: CEPA - Existing Substances Program under CEPA
CA: PCPA - Pest Control Products Act
JP: CSCL - Chemical Substances Control Law
OECD: HPVC - HPV Chemicals Programme
US: EPA HPVC - HPV Chemical Challenge Programme
US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
US: TSCA - Toxic Substances Control Act
Any other
No regulatory purpose
Note: for a REACH dossier, all information should be part of the dossier,
i.e. all flags should be selected or the default values should be used
1 2 3 4 5 6 7 8
Select data protection flags
< Back
Next >
Finish
Cancel

Appendix 4 Completing the dossier header

Having identified your submission context according to Appendix 2, the following subchapters explain how to take the final step during dossier creation for each submission context. In case further information is needed, go to Appendix 5.

Appendix 4.1 Single, Initial Submission

Figure 25: Single, Initial Submission

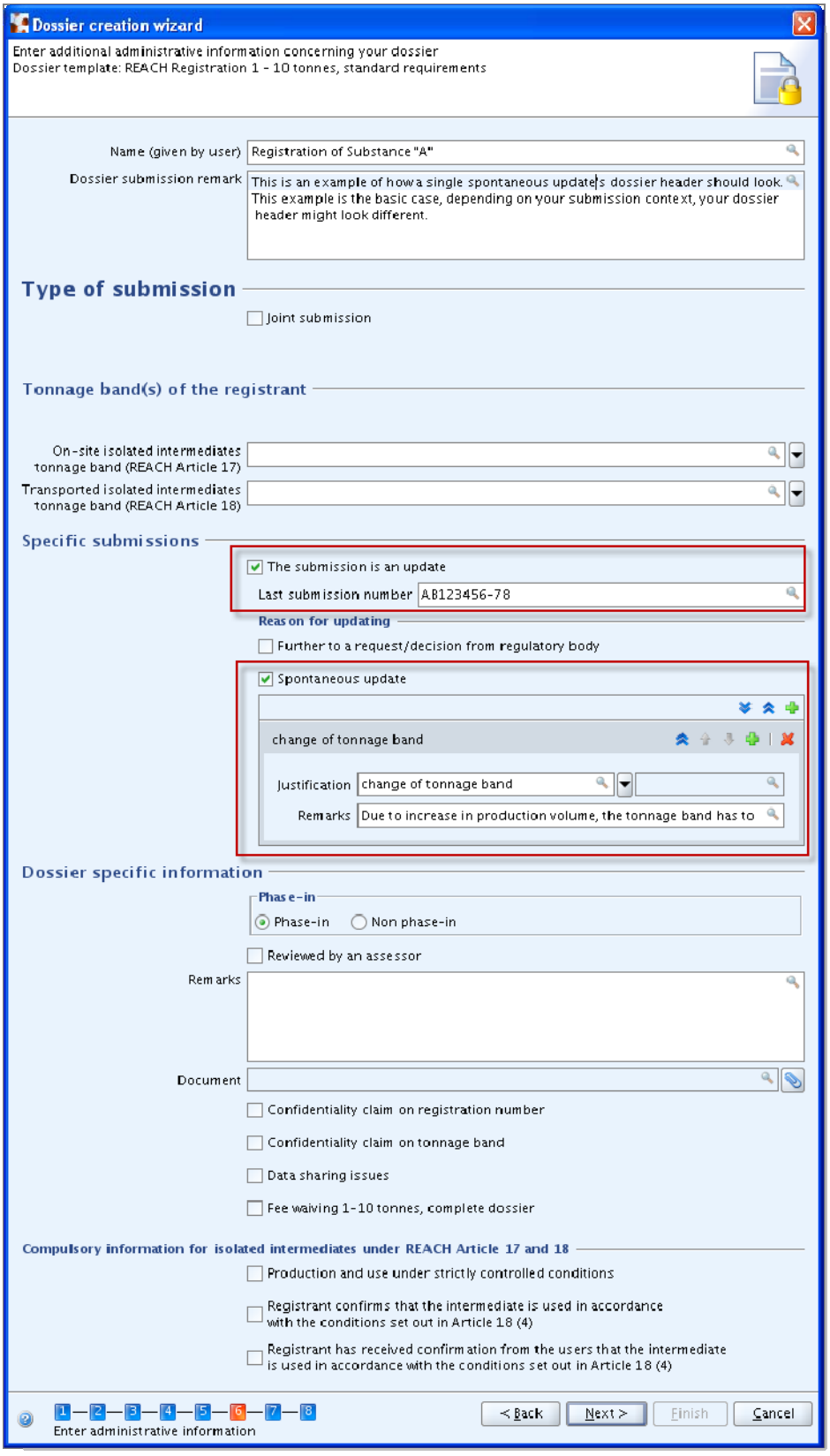

Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a single initial submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Tonnage band(s) of the registrant
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔

Checklist	✔	Checklist	✔
1, On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		4, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
2, Was the submission reviewed by an assessor? This information is not compulsory.		5, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
3, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1			

Appendix 4.2 Single Submission, Spontaneous Update

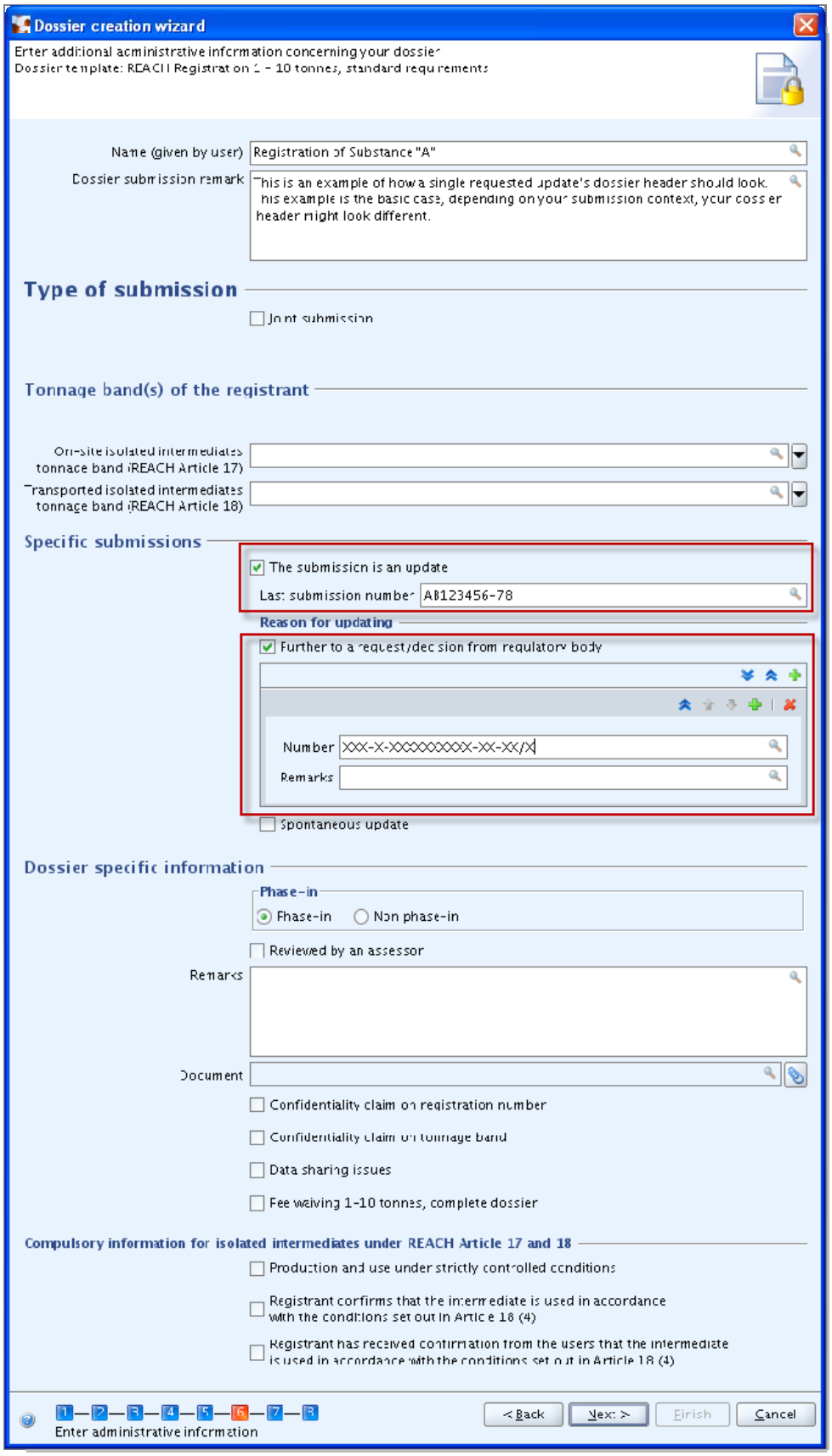
Figure 26: Single Submission, Spontaneous Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a single spontaneous update's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Tonnage band(s) of the registrant
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Last submission number
A.B123456-78
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage band has to
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
1, On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		5, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	
2, Last submission number must be indicated. For a spontaneous update, this will be the submission number associated with the most recent registration for that substance. (For registrations derived from a NONS claim and other special cases, see Appendix 5.3)		6, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
3, Justification for the spontaneous update must be provided. Appendix 5.3.3.2		7, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
4, Was the submission reviewed by an assessor? This information is not compulsory.		8, Make sure that you are using the assigned EC number. 0	

Appendix 4.3 Single Submission, Requested Update

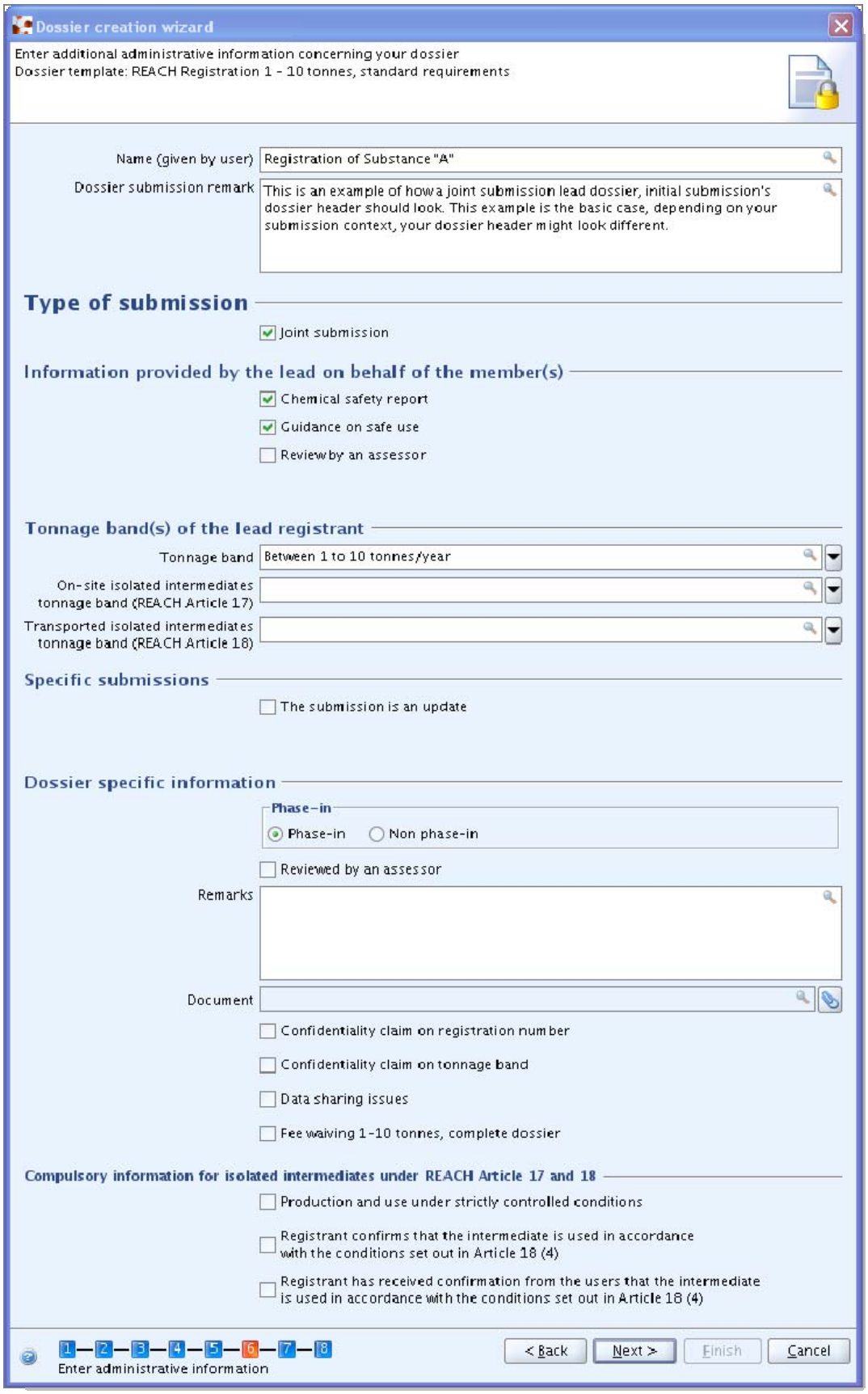
Figure 27: Single Submission, Requested Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a single requested update's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Tonnage band(s) of the registrant
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Last submission number
AB123456-78
Reason for updating
Further to a request/decision from regulatory body
Number
XXX-X-XXXXXXXXX-XX-XX/X
Remarks
Spontaneous update
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
1, On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		6, If the Requested Update is for a previously registered substance, make sure that the required regulatory identifiers were included in Section 1.3 of your substance dataset. Appendix 1.4	
2, Transported Isolated Intermediate Tonnage Band		7, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
3, Last submission number must be indicated. For a Technical Completeness Check (TCC) update (i.e. further information being submitted following a TCC failure), this will be the submission number associated with the dossier that failed TCC. (For other types of regulatory update see Appendix 5.3)		8, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
4, The Communication Number must be indicated. In the case of a TCC failure this will be the communication number provided in the letter which requested further information. For further information, please see Appendix 5.3.1 or Appendix 5.3.3.1.		9, Make sure that you are using the assigned EC number. 0	
5, Was the submission reviewed by an assessor This information is not compulsory.		10, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	

Appendix 4.4 Joint Submission Lead, Initial Submission

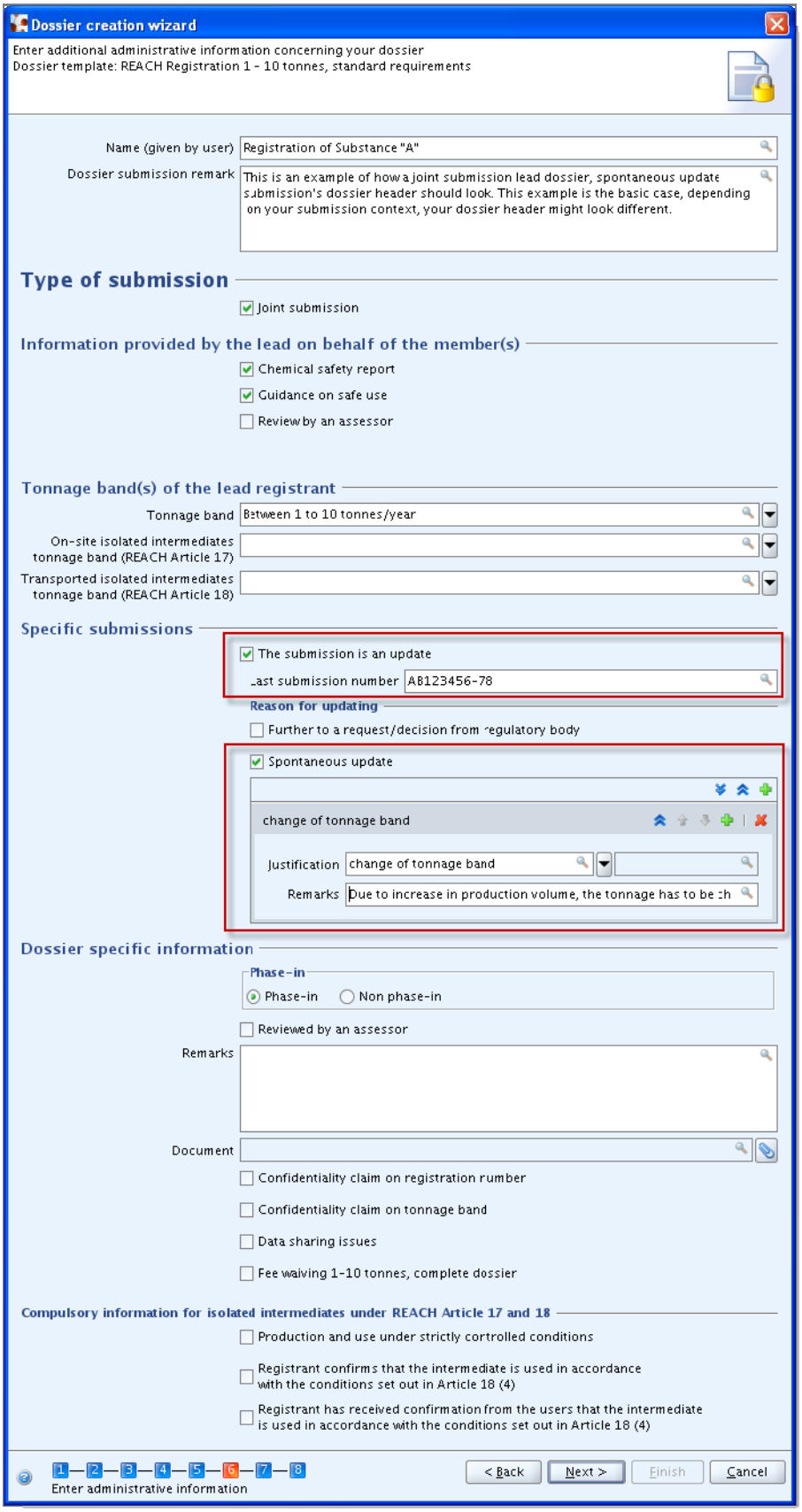
Figure 28: Joint Submission Lead, Initial Submission


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a joint submission lead dossier, initial submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band(s) of the lead registrant
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
1, Joint submission checkbox must be ticked Appendix 5.2		6, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	
2, “Chemical Safety Report”: tick this box if you are supplying the CSR on behalf of members.		7, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
3, “Guidance on Safe Use”: tick this box if you are supplying the Guidance on Safe Use on behalf of members.		8, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
4, “Review by Assessor”: this information is not part of the Business Rule check.		9, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
5, Information on tonnage band: When acting as the lead in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists. Note: The overall tonnage band of the Joint Submission is determined by the IUCLID 5 template that was used			

Appendix 4.5 Joint Submission Lead, Spontaneous Update

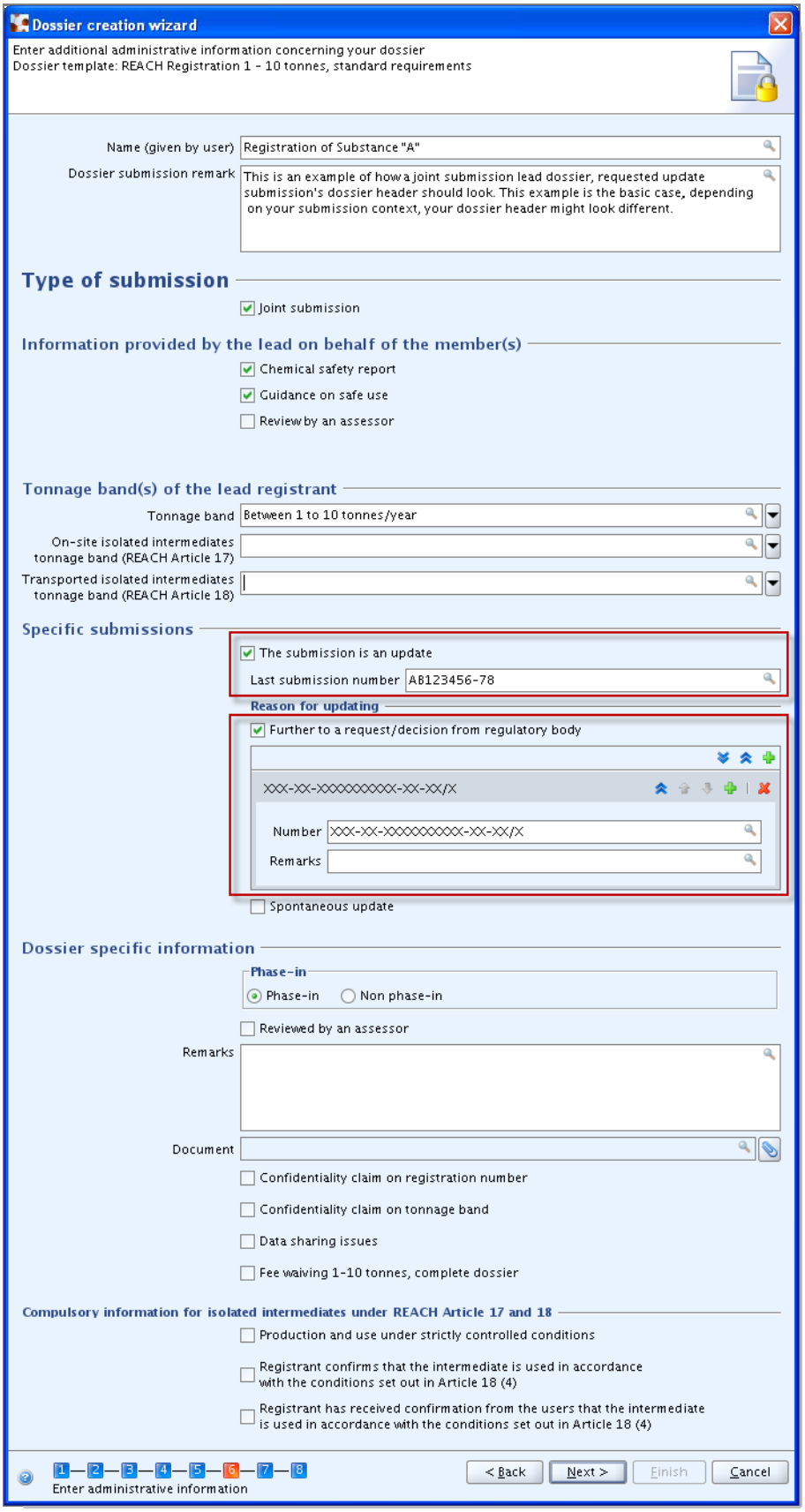
Figure 29: Joint Submission Lead, Spontaneous Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a joint submission lead dossier, spontaneous update submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band(s) of the lead registrant
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Last submission number
AB123456-78
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage has to be ch
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
1, Joint Submission checkbox must be ticked. Appendix 5.2		7, Last submission number must be indicated. For a spontaneous update, this will be the submission number associated with the most recent registration for that substance. (For registrations derived from a NONS claim and other special cases, see Appendix 5.3)	
2, “Chemical Safety Report”: tick this box if you are supplying the CSR on behalf of members.		8, Justification for Spontaneous Update must be provided. Chapter Appendix 5.3.3.2	
3, “Guidance on Safe Use”: tick this box if you are supplying the Guidance on Safe Use on behalf of members.		9, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	
4, “Review by Assessor”: this information is not part of the Business Rule check.		10, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
5, Information on tonnage band: When acting as the lead in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists. Note: The overall tonnage band of the Joint Submission is determined by the IUCLID 5 template that was used		11, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
6, Make sure that you are using the assigned EC number. 0		12, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	

Appendix 4.6 Joint Submission Lead, Requested Update

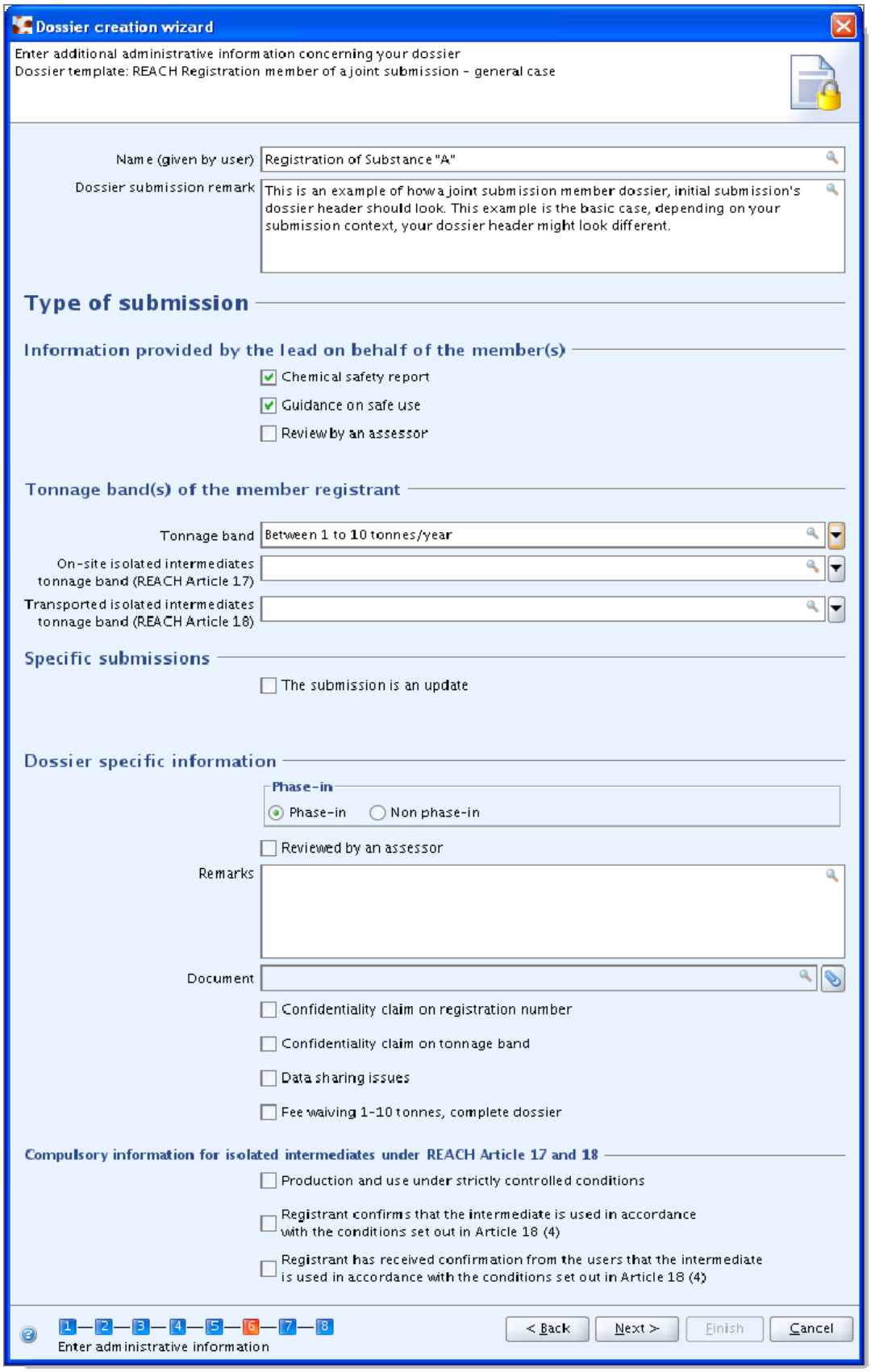
Figure 30: Joint Submission Lead, Requested Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a joint submission lead dossier, requested update submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band(s) of the lead registrant
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Last submission number
AB123456-78
Reason for updating
Further to a request/decision from regulatory body
XXX-XX-XXXXXXXXX-XX-XX/X
Number
XXX-XX-XXXXXXXXX-XX-XX/X
Remarks
Spontaneous update
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
Joint Submission checkbox must be ticked. Appendix 5.2		8, The Communication Number must be indicated. In the case of a TCC failure this will be the communication number provided in the letter which requested further information. For further information, please see Appendix 5.3.1 or Appendix 5.3.3.1.	
2, “Chemical Safety Report”: tick this box if you are supplying the CSR on behalf of members.		9, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	
3, “Guidance on Safe Use”: tick this box if you are supplying the Guidance on Safe Use on behalf of members.		10, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
4, “Review by Assessor”: this information is not part of the Business Rule check.		11, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
5, Information on tonnage band: When acting as the lead in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists. Note: The overall tonnage band of the Joint Submission is determined by the IUCLID 5 template that was used		12, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
6, Make sure that you are using the assigned EC number. 0		13, If the Requested Update is for a previously registered substance, make sure that the required regulatory identifiers were included in Section 1.3 of your substance dataset. Appendix 1.4	
7, Last submission number must be indicated. For a Technical Completeness Check (TCC) update (i.e. further information being submitted following a TCC failure), this will be the submission number associated with the dossier that failed TCC. (For other types of regulatory update see Appendix 5.3)			

Appendix 4.7 Joint Submission Member, Initial Submission

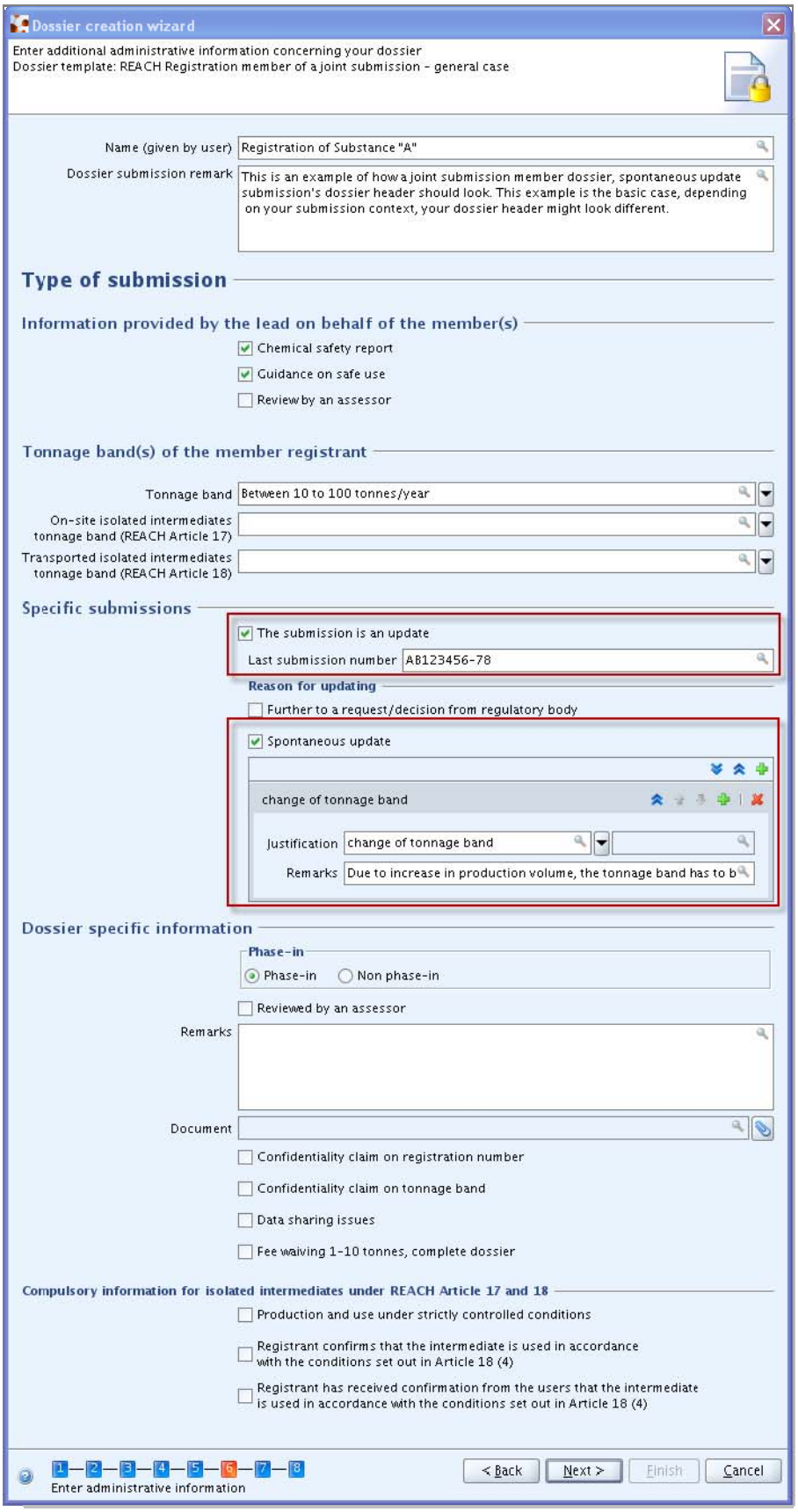
Figure 31: Joint Submission Member, Initial Submission


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration member of a joint submission - general case
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a joint submission member dossier, initial submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band(s) of the member registrant
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
Joint Submission checkbox must be ticked. Appendix 5.2		6, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	
2, “Chemical Safety Report”: tick this box if the CSR was supplied by the lead on your behalf and as such you have not added a CSR to your own dataset. Do not tick this box if you are providing a CSR independently from the lead, i.e. within your own dossier.		7, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
3, “Guidance on Safe Use”: tick this box if the Guidance on Safe Use was supplied by the lead on your behalf and as such you have not added Guidance on Safe Use to your own dataset. Do not tick this box if you are providing Guidance on Safe Use independently from the lead, i.e. within your own dossier.		8, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
4, “Review by Assessor”: this information is not part of the Business Rule check.		9, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
5, Information on tonnage band: When acting as a member in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.			

Appendix 4.8 Joint Submission Member, Spontaneous Update

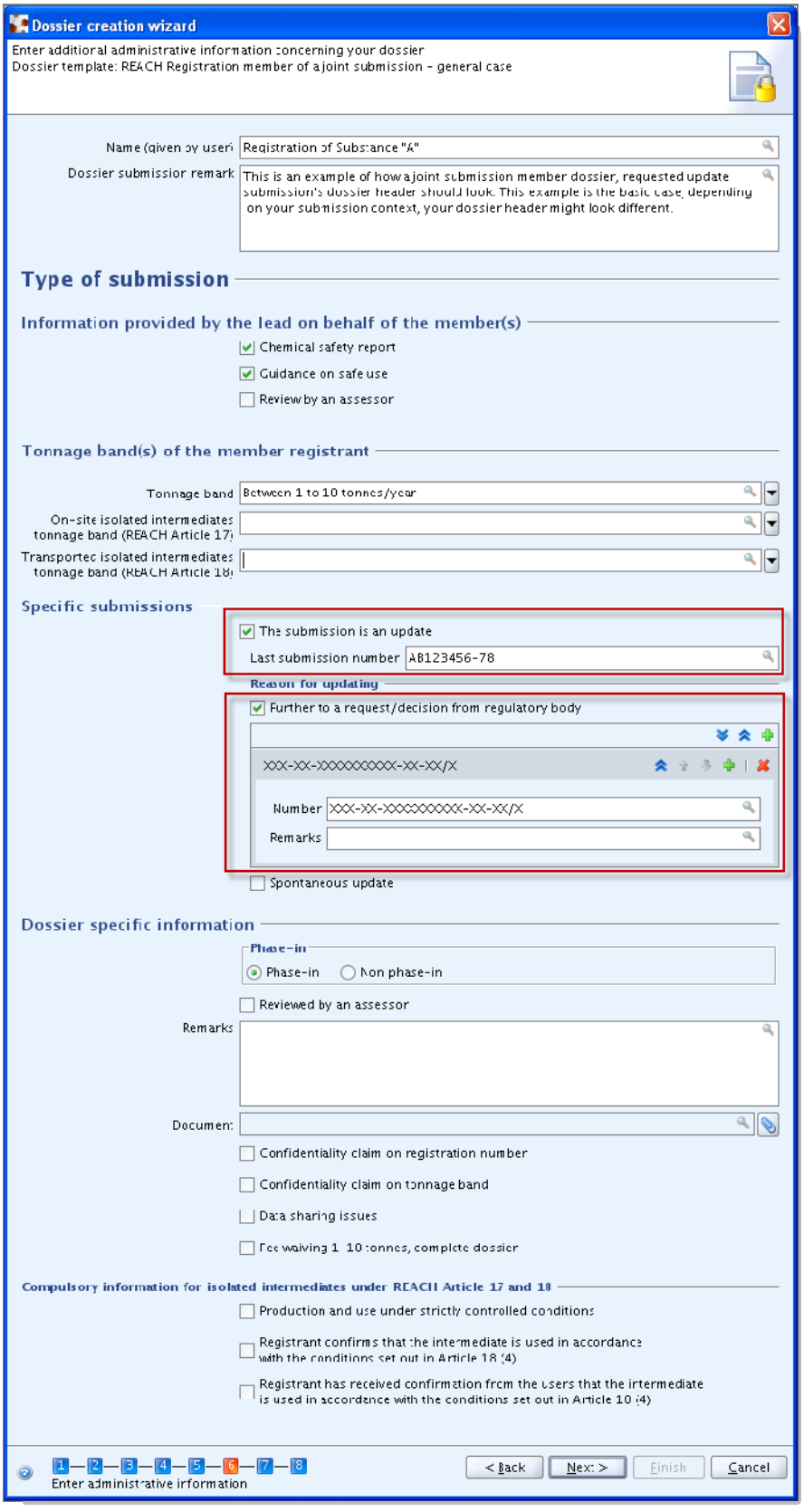
Figure 32: Joint Submission Member, Spontaneous Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration member of a joint submission - general case
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a joint submission member dossier, spontaneous update submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band(s) of the member registrant
Tonnage band
Between 10 to 100 tonnes/year
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Last submission number
A8123456-78
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage band has to b
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
1, Joint Submission checkbox must be ticked. Appendix 5.2		7, Justification for Spontaneous Update must be provided. Chapter Appendix 5.3.3.2	
2, “Chemical Safety Report”: tick this box if the CSR was supplied by the lead on your behalf and as such you have not added a CSR to your own dataset. Do not tick this box if you are providing a CSR independently from the lead, i.e. within your own dossier.		8, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	
3, “Guidance on Safe Use”: tick this box if the Guidance on Safe Use was supplied by the lead on your behalf and as such you have not added Guidance on Safe Use to your own dataset. Do not tick this box if you are providing Guidance on Safe Use independently from the lead, i.e. within your own dossier.		9, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
4, “Review by Assessor”: this information is not part of the Business Rule check.		10, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
5, Information on tonnage band: When acting as a member in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		11, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
6, Last submission number must be indicated. For a spontaneous update, this will be the submission number associated with the most recent registration for that substance. (For registrations derived from a NONS claim and other special cases, see Appendix 5.3)		12, Make sure that you are using the assigned EC number. 0	

Appendix 4.9 Joint Submission Member, Requested Update

Figure 33: Joint Submission Member, Requested Update


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration member of a joint submission - general case
Name (given by user)
Registration of Substance "A"
Dossier submission remark
This is an example of how a joint submission member dossier, requested update submission's dossier header should look. This example is the basic case, depending on your submission context, your dossier header might look different.
Type of submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band(s) of the member registrant
Tonnage band
Between 1 to 10 tonnes/year
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Last submission number
AB123456-78
Reason for updating
Further to a request/decision from regulatory body
XXX-XX-XXXXXXXXXX-XX-XX/X
Number
XXX-XX-XXXXXXXXXX-XX-XX/X
Remarks
Spontaneous update
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Checklist	✔	Checklist	✔
1, The Joint Submission checkbox must be ticked. Appendix 5.2		8, Do you want to claim confidentiality on the registration number or for the Tonnage Band of the submission? Appendix 5.4.1	
2, “Chemical Safety Report”: tick this box if the CSR was supplied by the lead on your behalf and as such you have not added a CSR to your own dataset. Do not tick this box if you are providing a CSR independently from the lead, i.e. within your own dossier.		9, Have there been any “Data Sharing Issues”? This information is not part of the Business Rule check.	
3, “Guidance on Safe Use”: tick this box if the Guidance on Safe Use was supplied by the lead on your behalf and as such you have not added Guidance on Safe Use to your own dataset. Do not tick this box if you are providing Guidance on Safe Use independently from the lead, i.e. within your own dossier.		10, Do you want to claim a Fee-waiver for substances in the 1-10 tonnage band? Appendix 5.4.2	
4, “Review by Assessor”: this information is not part of the Business Rule check.		11, If the submission includes registration of an intermediate, the “Specific Information for Isolated Intermediates” part must be filled out. Appendix 5.5	
5, Information on tonnage band: When acting as a member in a joint submission, these fields are used to indicate your own registration tonnage bands. On-Site Isolated Intermediate Tonnage Band / Transported Isolated Intermediate Tonnage Band: If your registration includes either of these intermediate registration types, you must indicate your relevant tonnage band(s) in the drop down lists.		12, Make sure that you are using the assigned EC number. 0	
6, Last submission number must be indicated. For a Technical Completeness Check (TCC) update (i.e. further information being submitted following a TCC failure), this will be the submission number associated with the dossier that failed TCC. (For other types of regulatory update see Appendix 5.3)		13, If the Requested Update is for a previously registered substance, make sure that the required regulatory identifiers were included in Section 1.3 of your substance dataset. Appendix 1.4	
7, The Communication Number must be indicated. In the case of a TCC failure this will be the communication number provided in the letter which requested further information. For further information, please see Appendix 5.3.1 or Appendix 5.3.3.1.			

Appendix 5 Further information on the IUCLID 5 Dossier Header

The dossier header has a significant impact:

- On the processing of the dossier
- On the calculation of fees and preparation of the invoice.

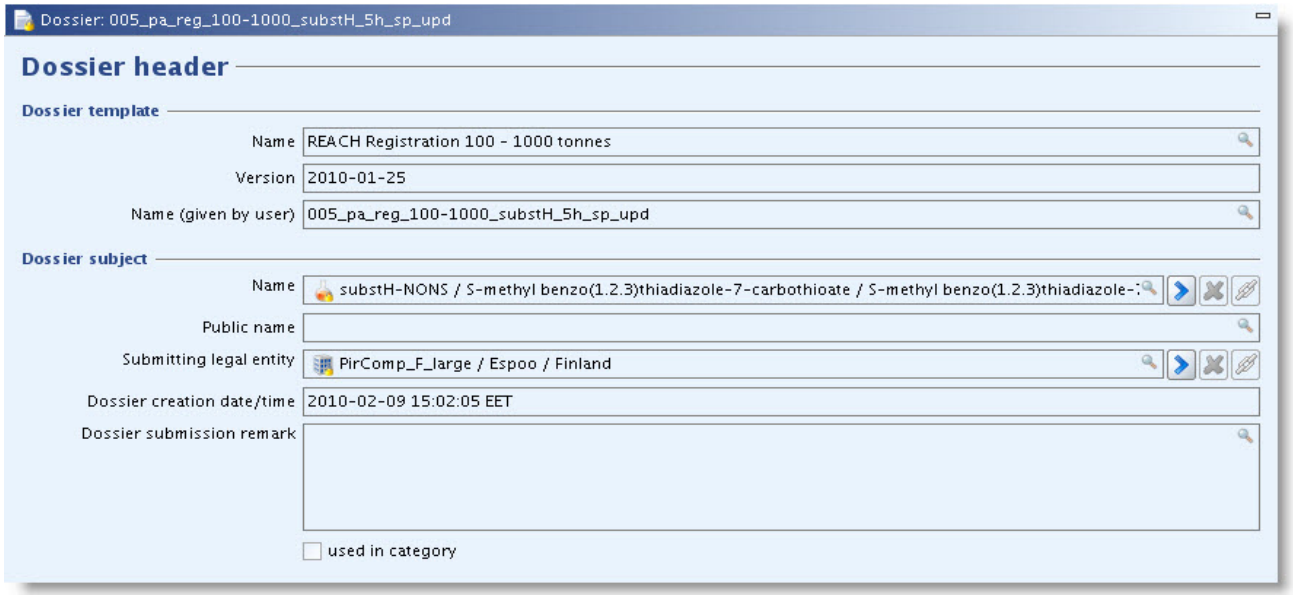
During the IUCLID 5 dossier creation procedure, the dossier creation wizard requests the user to “Enter additional administrative information concerning your dossier” in the 6th step.

To create a dossier in IUCLID 5, the user should start from the substance dataset, select the template corresponding to the submission (e.g. REACH Registration 10 - 100 tonnes, REACH PPORD, …), and follow the dossier creation wizard.

Note the guidance in Appendix 1.1 bullet point 2 with respect to the legal entity of the IUCLID 5 user. In Step 5 of the dossier creation, the user will see the legal entity the dossier is being created for and once the dossier is created, the user can view the dossier header, where the name of the submitting legal entity is shown.

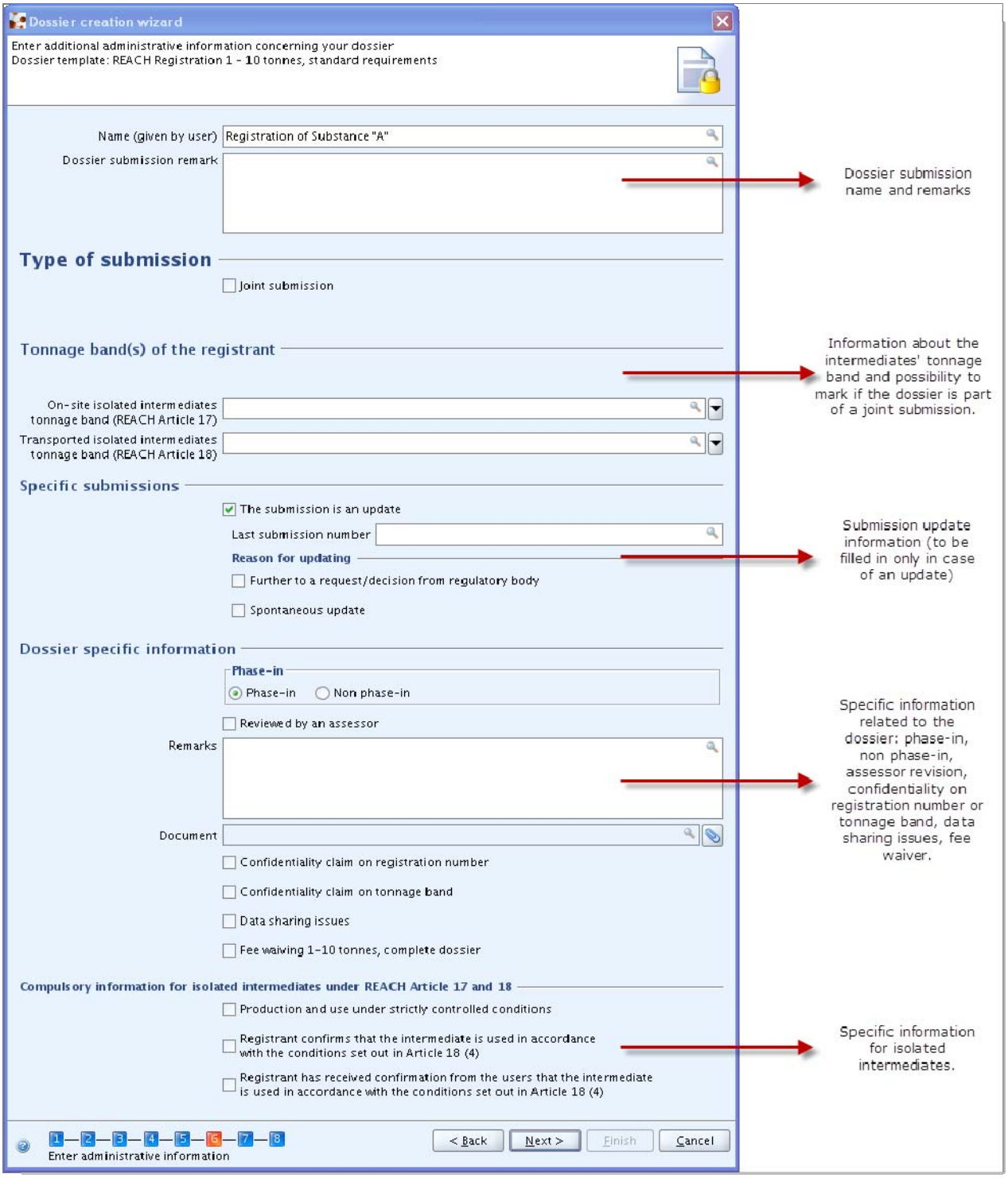
This information will then be embedded in the IUCLID 5 dossier header.
Below is an example (Figure 34) of how a dossier header appears once the dossier is created.

Figure 34: Dossier header in IUCLID 5



In the following pages, a detailed guide on how to fill in properly the information requested during the 6th step of the dossier creation wizard is given. The screen at this step is divided in five parts (Figure 35).

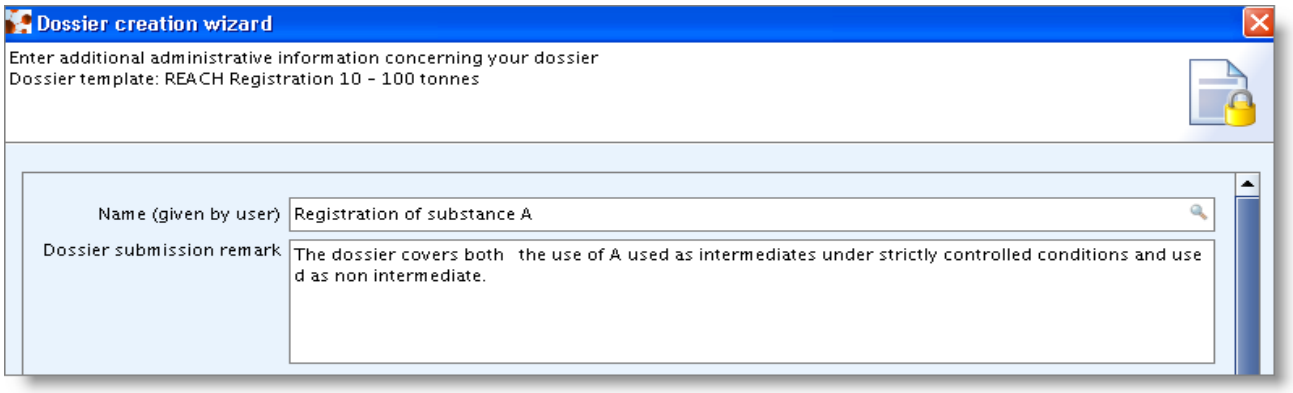
Figure 35: Step 6 of the Dossier Creation Wizard


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 1 - 10 tonnes, standard requirements
Name (given by user)
Registration of Substance "A"
Dossier submission remark
Dossier submission name and remarks
Type of submission
Joint submission
Tonnage band(s) of the registrant
Information about the intermediates' tonnage band and possibility to mark if the dossier is part of a joint submission.
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)
Specific submissions
The submission is an update
Last submission number
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
Submission update information (to be filled in only in case of an update)
Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving 1-10 tonnes, complete dossier
Specific information related to the dossier: phase-in, non phase-in, assessor revision, confidentiality on registration number or tonnage band, data sharing issues, fee waiver.
Compulsory information for isolated intermediates under REACH Article 17 and 18
Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Specific information for isolated intermediates.
1 2 3 4 5 6 7 8
Enter administrative information
< Back
Next >
Finish
Cancel

Appendix 5.1 Dossier submission name and remarks (dossier header part 1)

The first part allows you to specify the name of the dossier (Figure 36) as well as any additional information you want to point out.

Figure 36: Specifying the name of the dossier


Dossier creation wizard
Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 10 - 100 tonnes
Name (given by user)
Registration of substance A
Dossier submission remark
The dossier covers both the use of A used as intermediates under strictly controlled conditions and use d as non intermediate.

Appendix 5.2 Type of Submission (dossier header part 2)

The second part of the dossier header is where information about involvement in joint submission (for a lead dossier) and possible inclusion of intermediates in the registration can be indicated.

If the dossier is a part of a joint submission, the registrant should mark the “Joint submission” tick box. In case the box is marked, further information is required about what is provided by the lead registrant. Please note that this tick box is not available in dossier templates for member registrants.

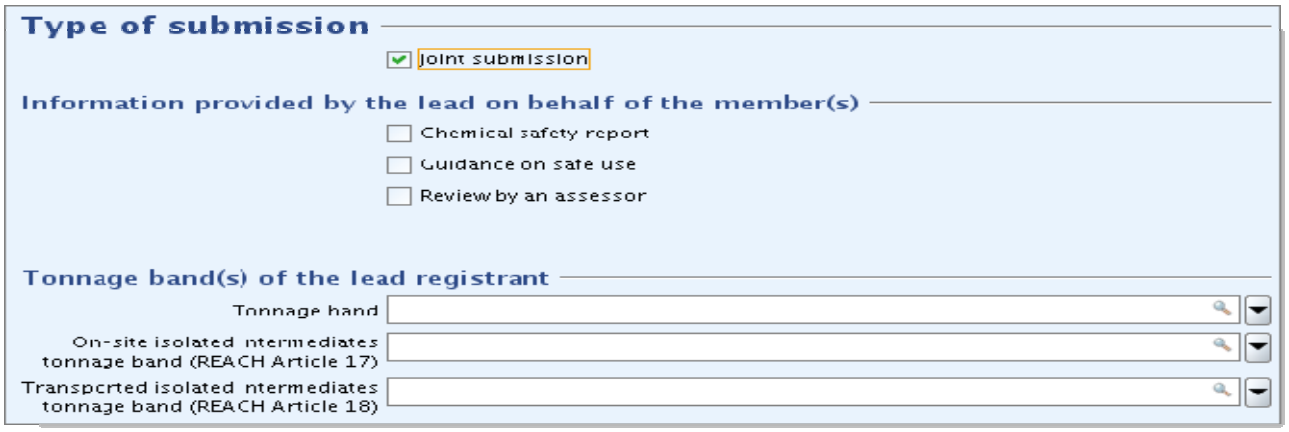
Please note: Tick the Chemical Safety Report box / Guidance on Safe Use box as a lead registrant only if you submit them on behalf of your members, while as a member registrant only if they are supplied by the lead on your behalf and as such you have not added them to your own dataset. Do not tick these boxes, if you are providing this information independently from the lead, i.e. within your own dataset.

While member registrants can with a simple spontaneous update change their status of relying on CSR and / or Guidance on Safe Use submitted by the lead registrant, lead registrants can only update this information from “not providing” to “providing”. This is implemented in order to avoid scenarios where member registrations would become incomplete after an update of the lead dossier.

When the “Joint Submission” tick box is marked, the “Tonnage band” pick list appears (for member dossiers it is available by default). In case of Joint Submissions, the IUCLID 5 template determines the Joint Submission tonnage band (lead registrant dossiers) or does not indicate a tonnage band at all (member dossiers). Therefore, the submitting company’s annual manufactured/imported tonnage of the substance can only be indicated in this “Tonnage band” field.

If the dossier is a combined submission for non-intermediate and intermediate use, the intermediate tonnage bands need to be indicated in this part of the dossier header.

Figure 37: Type of submission


Type of submission
Joint submission
Information provided by the lead on behalf of the member(s)
Chemical safety report
Guidance on safe use
Review by an assessor
Tonnage band(s) of the lead registrant
Tonnage band
On-site isolated intermediates tonnage band (REACH Article 17)
Transported isolated intermediates tonnage band (REACH Article 18)

Appendix 5.3 Submission update information (dossier header part 3)

It is important to identify whether the dossier should be submitted as an update of a previous dossier or not. Please note the following:

If a submitted dossier is marked as an update although it should not be, then it cannot be processed by REACH-IT and the “Submission failure/submission rule violation” message is sent to your REACH-IT inbox.

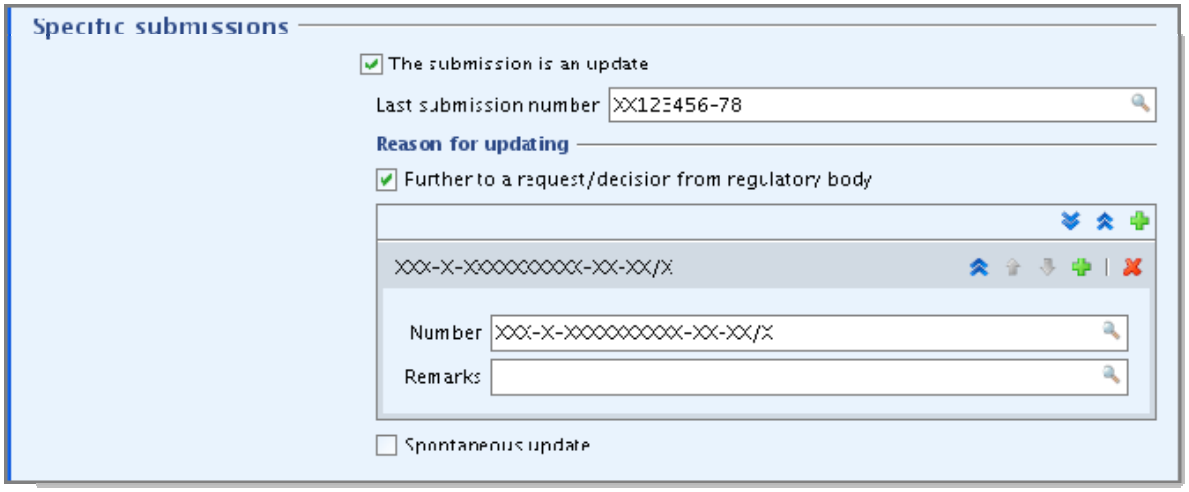
The following situations are the only situations where the submission should be considered as an update:

Appendix 5.3.1 Requested Update for an Incomplete Initial Submission

A registration dossier has been sent before for the same substance, but, although it passed the business rule verification steps in REACH-IT, the registration was considered as incomplete by ECHA during completeness check. The submission of an updated dossier in this case is meant to fulfil the request for further information made by the Agency within a set deadline. Under these circumstances: the last submission number (i.e. the one attributed to the dossier which resulted in the request for further information) must be reported in the “Last submission number” field; the checkbox “Further to a request/decision from regulatory body” in IUCLID must be selected (
Figure 38), and the communication number indicated in the request for further information must be entered in the adjacent “Number” field in IUCLID (see
Figure 38).

This only applies to submissions which were considered incomplete by the Agency during the completeness check and which resulted in a letter titled ‘Request for further information on your registration under Regulation (EC) No. 1907/2006’. If you receive a communication of Business Rule validation failure then you should submit the same type of dossier (initial or spontaneous update) as the one that failed Business Rule validation.

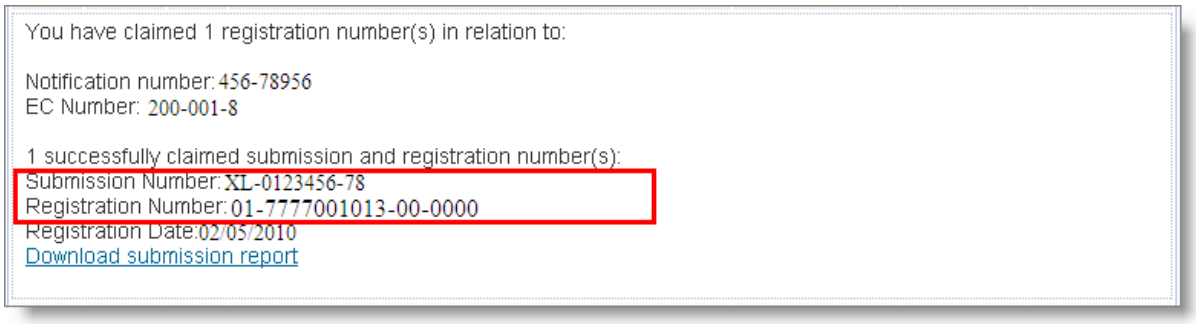
Figure 38: IUCLID screen with reason for updating



Appendix 5.3.2 Updating a Substance Notified Under Previous Legislation (NONS)

The substance is a notified substance under Directive 67/548/EEC (considered as being registered by the claimant under REACH). Before proceeding, you should claim the registration number following the information given in ECHA web site related to the NONS (http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/nons). If the claim is successful, you will receive in your REACH-IT mailbox both the registration number and the submission number (Figure 39).

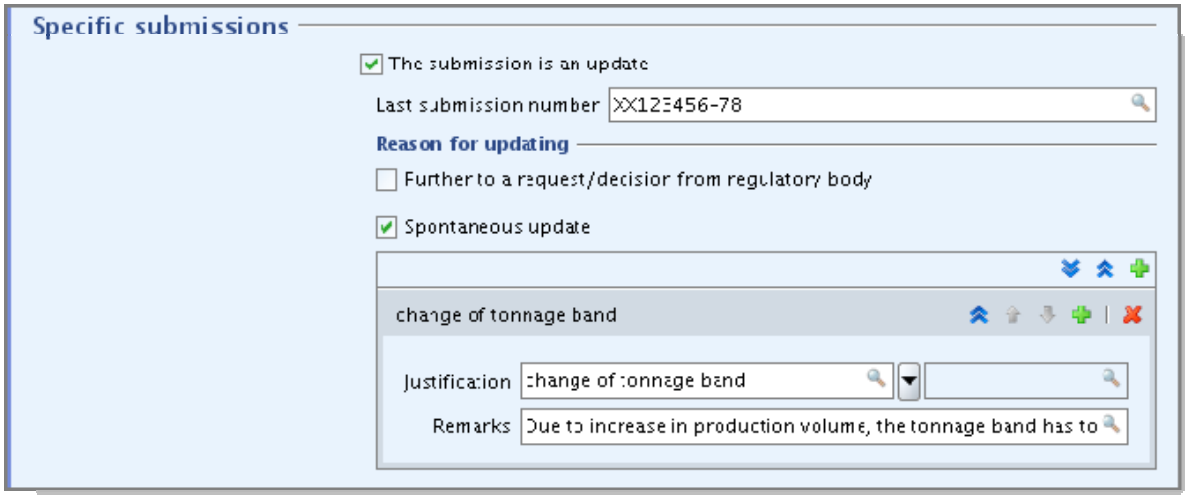
Figure 39: REACH-IT message for successful NONS claim


You have claimed 1 registration number(s) in relation to:
Notification number: 456-78956
EC Number: 200-001-8
1 successfully claimed submission and registration number(s):
Submission Number: XL-0123456-78
Registration Number: 01-7777001013-00-0000
Registration Date: 02/05/2010
Download submission report

In order to update your dossier, you should proceed as follows:

- The registration number received should be reported in section 1.3 of the IUCLID 5 dossier.
- The notification number (NCD number) should be reported in section 1.3 of the IUCLID 5 dossier.
- In the dossier header you should indicate, in the “Last submission number” field (Figure 40), the Submission number as indicated in the “Registration number successfully claimed” message.
- Select the checkbox “Spontaneous update” and specify the reason for the update by selecting it from the drop down list in the “Justification” field (Figure 40).

Figure 40: Updating previous NONS after the claiming of the registration number.


Specific submissions
The submission is an update
Last submission number XX123456-78
Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification change of tonnage band
Remarks Due to increase in production volume, the tonnage band has to

Appendix 5.3.3 Previously Registered Under REACH

The substance was previously registered by your company under REACH. In this case the submission number of the last complete dossier submitted for this substance or the submission number of your update which failed completeness check should be reported in the "Last submission number" field and the registration number should be indicated in the section 1.3 of the IUCLID 5 dossier.

It should also be reported whether the update is an update made on "request from regulatory body" (for example when an update should be submitted following an ECHA completeness check communication or an ECHA compliance check communication) or whether it is a spontaneous update. If the dossier is an update, it should be identified by all of the following information:

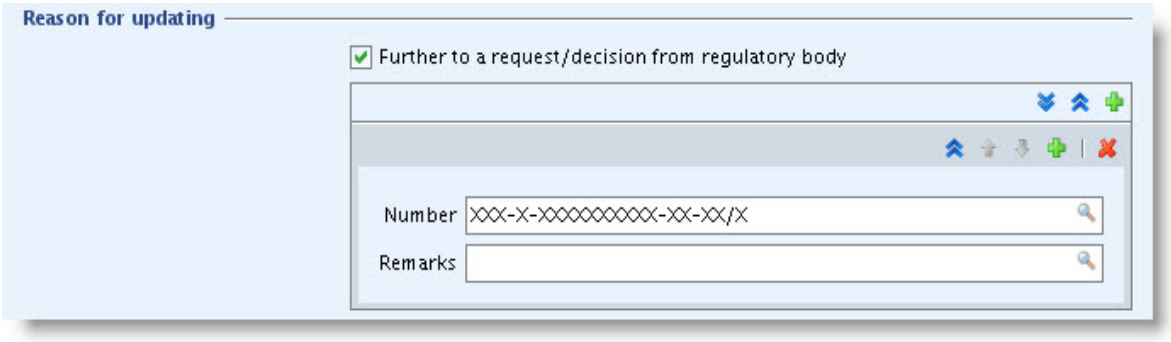
- Ticking the box "is the submission an update";
- Including the "last submission number" (the number to be given depends on the circumstances described in the succeeding paragraphs);
- Completing the "reason for updating" field.

If the above mentioned information is not provided, ECHA will not be able to process the dossier.

Appendix 5.3.3.1 Update on request

In case of an update made on request of a regulatory body, the checkbox "Further to a request/decision from regulatory body" must be selected and the communication number in the request letter must be entered in the adjacent "Number" field (Figure 41).

Figure 41: Reason for updating - further to a request/decision from regulatory body

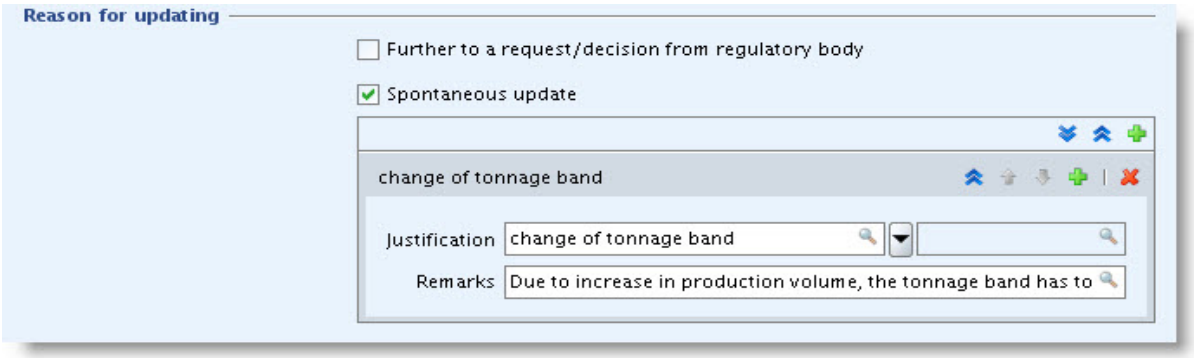


Appendix 5.3.3.2 Spontaneous update

In case of spontaneous update, the checkbox "spontaneous update" should be selected (Figure 42) and the reason for the update should be chosen from the drop down list in the "justification" field (Figure 42). The drop down list is reporting the following update reasons:

- Change in company identity (NB! This update reason cannot be used in the context of REACH-IT submissions.)
- Change in company role in the supply chain
- Change in composition of the substance
- Change of tonnage band
- New identified uses
- New uses advised against
- New knowledge of the risks for human health and /or environment
- Change in classification and labelling
- New or update of CSR or guidance on safe use
- New testing proposal
- Change in the access granted to information
- Prolongation of exemption period for PPORD
- New uses outside the supplier's conditions (DU obligations)
- Change in exemptions (DU obligations)
- Other

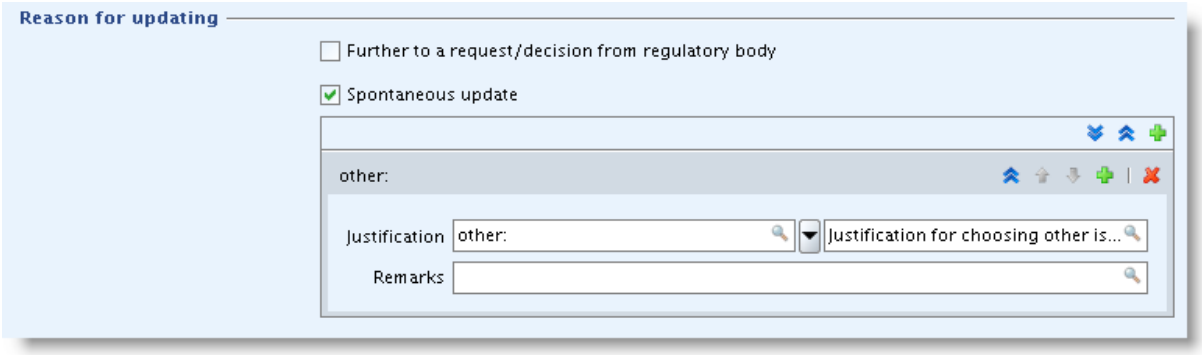
Figure 42: Reason for updating – spontaneous update


Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Due to increase in production volume, the tonnage band has to

If the reason of the spontaneous update is not listed in the drop down list (for example in case of manufacture cease), the entry “other:” should be selected and the information should be indicated in the corresponding field (Figure 43).

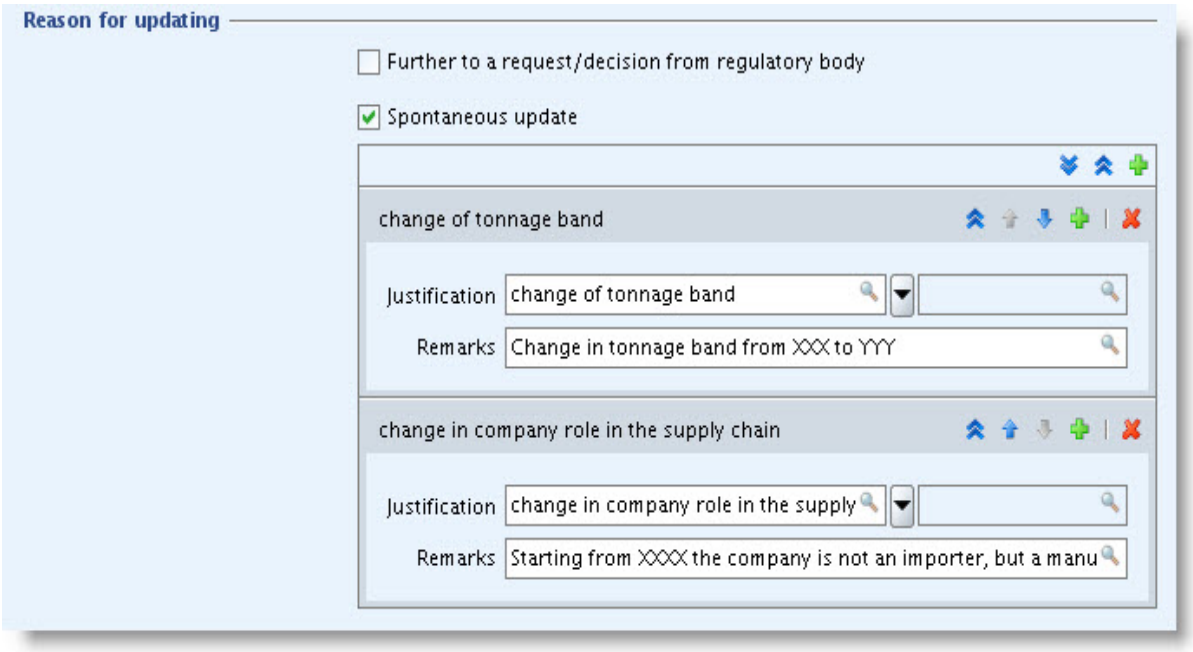
Please note that for technical reasons, if you are updating an individually submitted dossier to be part of a joint submission as a lead or member, you have to indicate “Change of tonnage band” as (one of) the reason(s) for updating your dossier. In case your actual tonnage band stays the same as for your previous submission, this will not trigger an invoice.

Figure 43: Reason for updating –spontaneous update (other justification)



Finally if you need to indicate more than one reason for updating your dossier, an additional repeatable block should be created for each reason (Figure 44). Please note that a justification has to be provided in all the blocks.

Figure 44: Several reasons for updating – spontaneous update

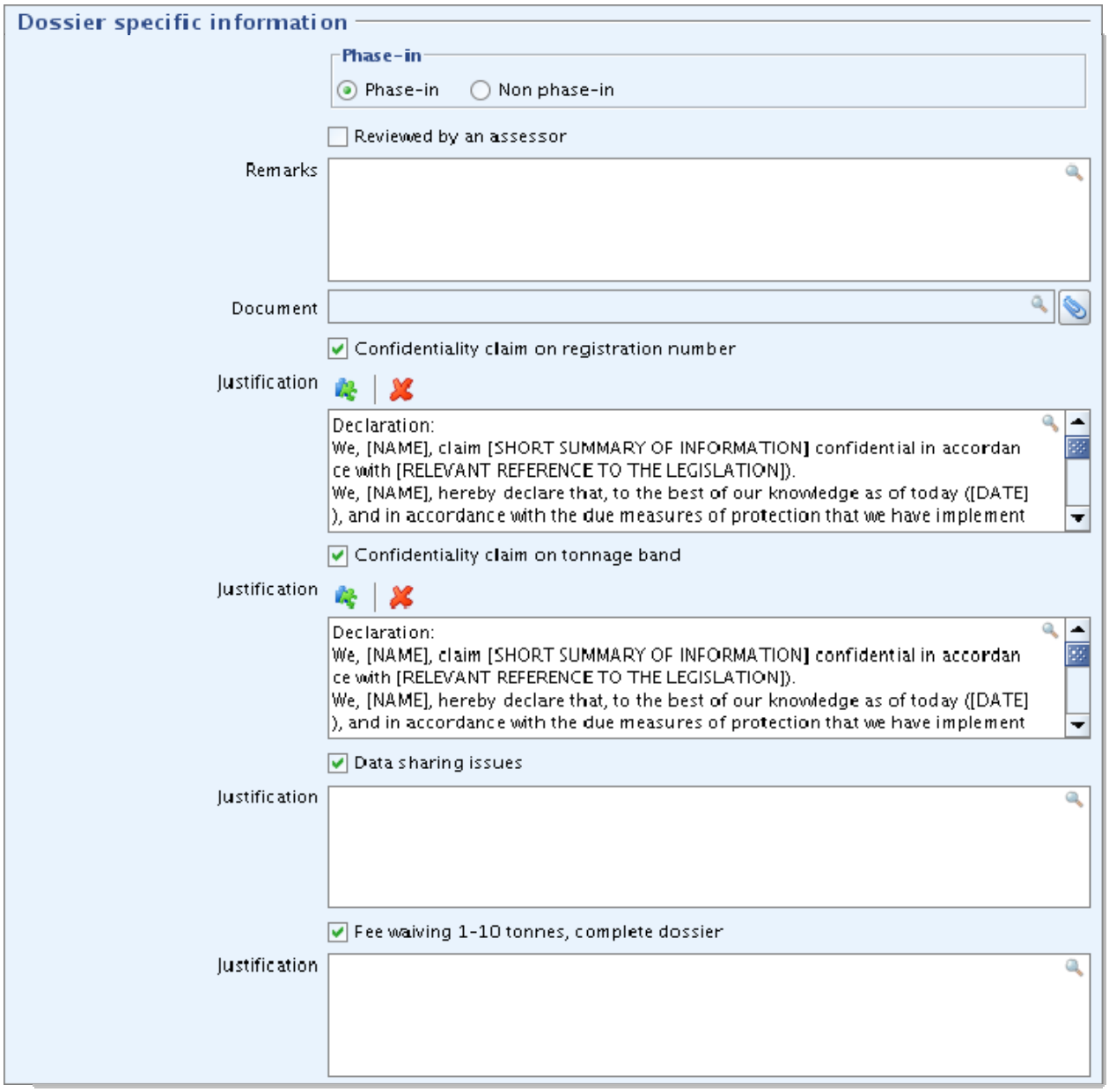

Reason for updating
Further to a request/decision from regulatory body
Spontaneous update
change of tonnage band
Justification
change of tonnage band
Remarks
Change in tonnage band from XXX to YYY
change in company role in the supply chain
Justification
change in company role in the supply
Remarks
Starting from XXXX the company is not an importer, but a manu

For more information on different types of registration dossiers and the related requirements, refer to the “Guidance on registration” - section 9 (guidance on update of dossier) [http://guidance.echa.europa.eu/].

Appendix 5.4 Specific information related to the dossier (dossier header part 4)

This part of the dossier header allows giving information about the phase-in "status" of the substance, along with more general information on the IUCLID 5 dossier submitted. As a general rule when one of the boxes of the block "registration dossier specific information" (review by an assessor, confidentiality claim on tonnage band, fee waiving…) is ticked, the associated free text field below the box should be filled in (example in Figure 45). For more information on how to complete this section of the dossier header, please consult the latest version of the Data Submission Manual 5 (How to Complete a Technical Dossier for Registrations and PPORD Notifications) available from the ECHA website (http://echa.europa.eu/support/dossier-submission-tools).

Figure 45: Registration dossier specific information


Dossier specific information
Phase-in
Phase-in
Non phase-in
Reviewed by an assessor
Remarks
Document
Confidentiality claim on registration number
Justification
Declaration:
We, [NAME], claim [SHORT SUMMARY OF INFORMATION] confidential in accordan
ce with [RELEVANT REFERENCE TO THE LEGISLATION]).
We, [NAME], hereby declare that, to the best of our knowledge as of today ([DATE]
), and in accordance with the due measures of protection that we have implement
Confidentiality claim on tonnage band
Justification
Declaration:
We, [NAME], claim [SHORT SUMMARY OF INFORMATION] confidential in accordan
ce with [RELEVANT REFERENCE TO THE LEGISLATION]).
We, [NAME], hereby declare that, to the best of our knowledge as of today ([DATE]
), and in accordance with the due measures of protection that we have implement
Data sharing issues
Justification
Fee waiving 1-10 tonnes, complete dossier
Justification

The phase-in status has to be marked by selecting either the “Phase-in” or the “Non phase-in” radio button.

Some of the information reported in this block and listed below directly influences the fee calculation; therefore they are part of the Business Rule check.

- Confidentiality request on the registration number
- Confidentiality request on tonnage band is made in the dossier
- There is a request of fee waiving

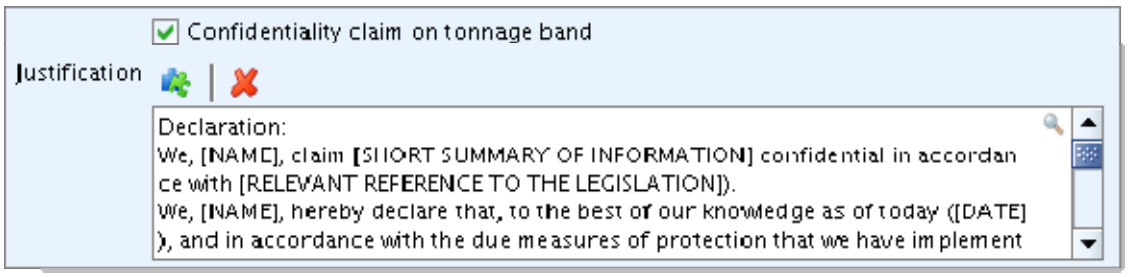
Appendix 5.4.1 Confidentiality

Confidentiality claim on the registration number or on the tonnage band

If the registrant wants to keep the registration number or the tonnage band for which he registers as confidential information, the relevant checkbox (either “Confidentiality claim on registration number” or “Confidentiality claim on tonnage band”) in the dossier header should be selected. For tonnage band, this is the only way to request the confidentiality, while the registration number can be flagged as confidential information in Section 1.3 also, in case of an update dossier. A justification must be provided (Figure 46) in both cases.

These fields cannot be used for any other type of confidentiality claims. When requesting confidentiality on the tonnage band or on the registration number, the relevant check box must be ticked, in any other case, the check box must not be ticked.

Figure 46: Confidentially request on the tonnage band


Confidentiality claim on tonnage band
Justification
Declaration:
We, [NAME], claim [SHORT SUMMARY OF INFORMATION] confidential in accordan
ce with [RELEVANT REFERENCE TO THE LEGISLATION]).
We, [NAME], hereby declare that, to the best of our knowledge as of today ([DATE]
), and in accordance with the due measures of protection that we have implement

The confidentiality flag in section 3.2 of IUCLID 5 cannot be used to request confidentiality for your tonnage band, because that section relates to the actual tonnage manufactured / imported, which is always treated as confidential information.

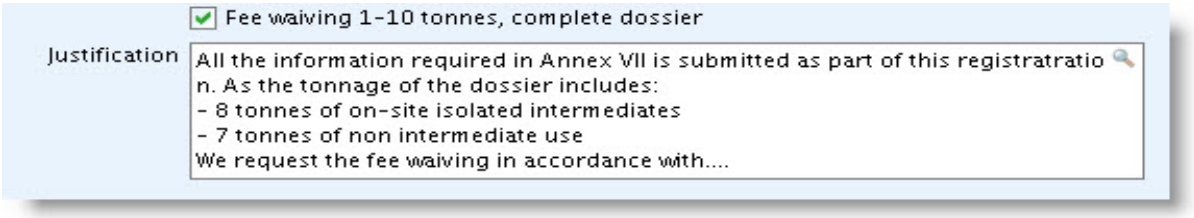
A registrant can request that certain information that is submitted to the Agency according to Art. 10 of the REACH regulation is not published on the internet because publication could be harmful for his or any other concerned party’s commercial interests.

All other confidentiality requests must be made in the relevant section of the substance dataset. A justification has to be provided for every confidentiality request. Further information can be found in the latest version of the “Data Submission Manual Part 16 – Confidentiality Claims: How to make confidentiality claims, and how to write Art 119(2) confidentiality claim justification” on the ECHA website (http://echa.europa.eu/support/dossier-submission-tools).

Appendix 5.4.2 Fee waiving

Request of fee waiving: Only in case a registration is made for a tonnage below 10 tonnes, an exemption of the fee can be requested if all information required by Annex VII of REACH is provided, in accordance with Art 3(1) and 4(1) of the Fee Regulation (EC 340/2008). In this case the checkbox “Fee waiving 1-10 tonnes, complete dossier” must be selected and a justification must be provided in the appropriate text box (Figure 47).

Figure 47: Request of fee waiving – tick box IUCLID


Fee waiving 1-10 tonnes, complete dossier
Justification
All the information required in Annex VII is submitted as part of this registratratio
n. As the tonnage of the dossier includes:
- 8 tonnes of on-site isolated intermediates
- 7 tonnes of non intermediate use
We request the fee waiving in accordance with....

Appendix 5.5 Specific information for isolated intermediates (dossier header part 5)

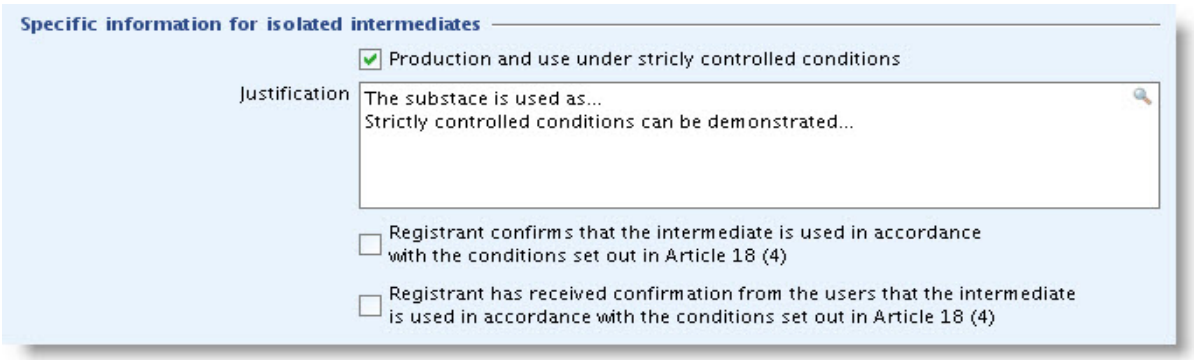
When the dossier covers also a volume used as isolated intermediate, specific information should be reported in the dossier header.

The exemption from standard information requirements only applies to isolated intermediates that are manufactured or used under strictly controlled conditions, and this will be regarded as claimed by the registrant only if the appropriate checkbox is selected (Figure 48). Please note that **both** checkboxes must be selected: “Registrant confirms that the intermediate…” and “Registrant has received confirmation…” in case of Registration of Transported Isolated Intermediates (Art. 18 registration).

Please note that the strictly controlled conditions will have to be carefully documented. More information can be found in the ‘Guidance on intermediates’ available from the ECHA website (http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation).

In addition, different information requirements apply to on-site and transported intermediates and more information can be found in the ‘Guidance for intermediates’ available from the ECHA website (http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation).

Figure 48: Tick boxes for isolated intermediates


Specific information for isolated intermediates
Production and use under stricly controlled conditions
Justification
The substace is used as...
Strictly controlled conditions can be demonstrated...
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)

When a dossier is made for a substance used both as isolated intermediates under strictly controlled conditions and as non intermediates, the fees will be calculated as the sum of

individual fees for intermediate and non intermediate (as if separate dossiers had been submitted).

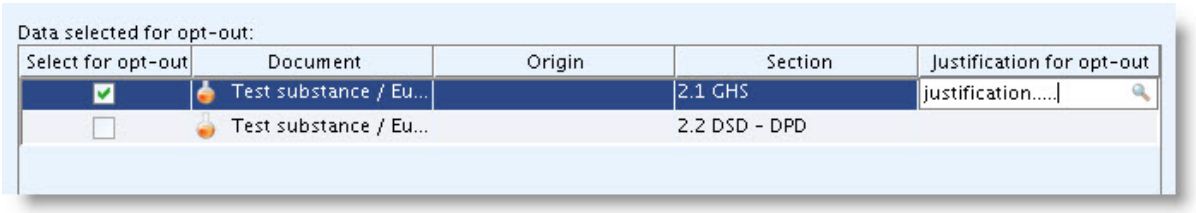
Appendix 5.6 Opt outs

Opt out from a joint submission: if the registrant is part of a joint submission and wants to opt out (according to Article 11(1) of the REACH Regulation) by submitting separately information, which should normally be submitted jointly, he should select the sections of the dossier for which the opt-out is requested at the 7th step of the dossier creation wizard.

Note that the 7th step of the dossier creation wizard will appear only if the registrant who is part of a joint submission has entered data into one or more of section 2 to 8 of his dataset. If no information from these sections is selected, then step 7 is skipped.

A justification should be provided in the last column for every section selected (Figure 49). Please note, that this step only available in case of a joint submission.

Figure 49: Indicating opt out in IUCLID

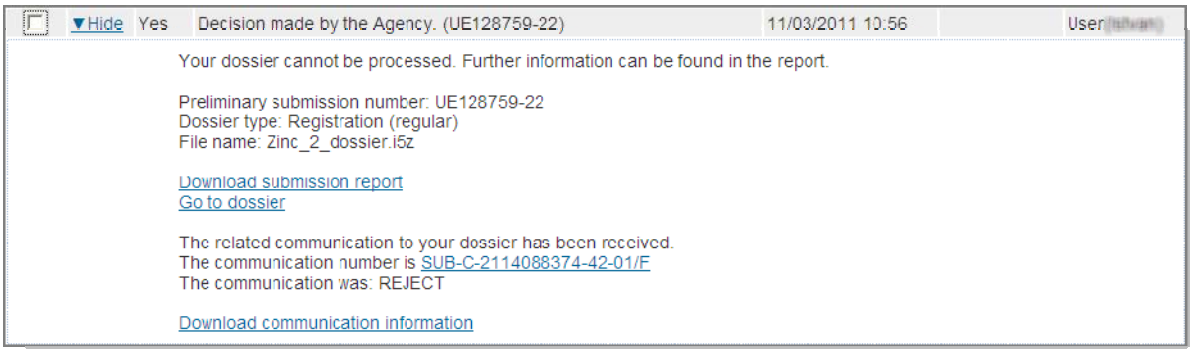


Appendix 6 Finding information about your submission

What happens when a dossier fails an automated business rule?

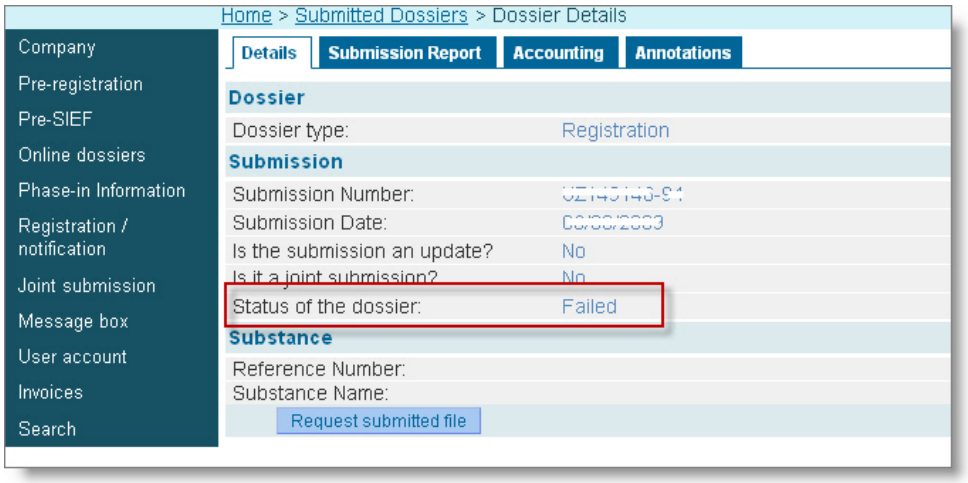
If the submitted dossier fails at the automated business rule step, REACH-IT immediately sends a message to the registrant in the REACH-IT mailbox. In this message, "Dossier business rule failure," the following information is displayed (see Figure 50).

Figure 50: REACH-IT message on BR failure – auto check


▼Hide
Yes
Decision made by the Agency. (UE128759-22)
11/03/2011 10:56
User
Your dossier cannot be processed. Further information can be found in the report.
Preliminary submission number: UE128759-22
Dossier type: Registration (regular)
File name: Zinc_2_dossier.i5z
Download submission report
Go to dossier
The related communication to your dossier has been received.
The communication number is SUB-C-2114088374-42-01/F
The communication was: REJECT
Download communication information

If you click the <Go to dossier> link, you will also notice that in the <Dossier details> tab, the status of the dossier has changed from <Pending> to <Failed> as shown here below (see Figure 51).

Figure 51: Status of a dossier in the dossier details tab



The complete list of the failed automated business rules is available by clicking the tab <Submission Report>. (see Figure 52 and Figure 53)

Figure 52: Tab for checking complete list of failed automated business rules

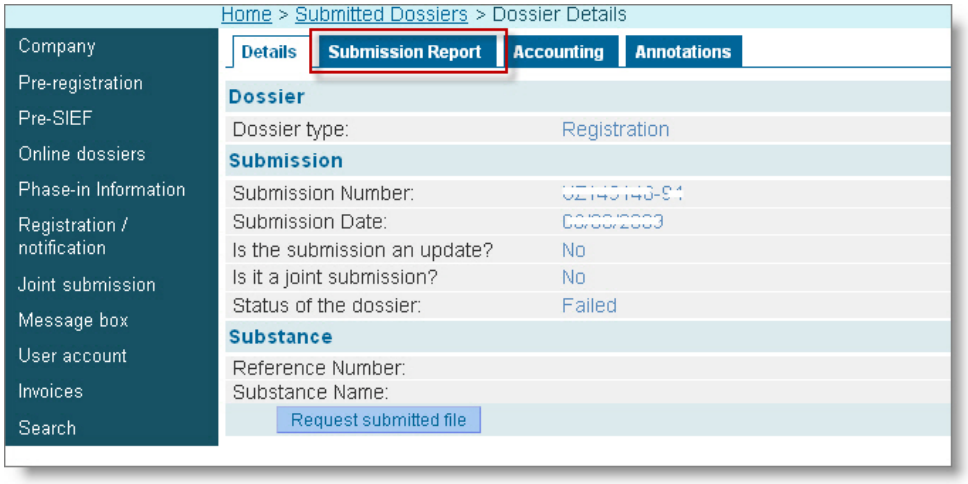
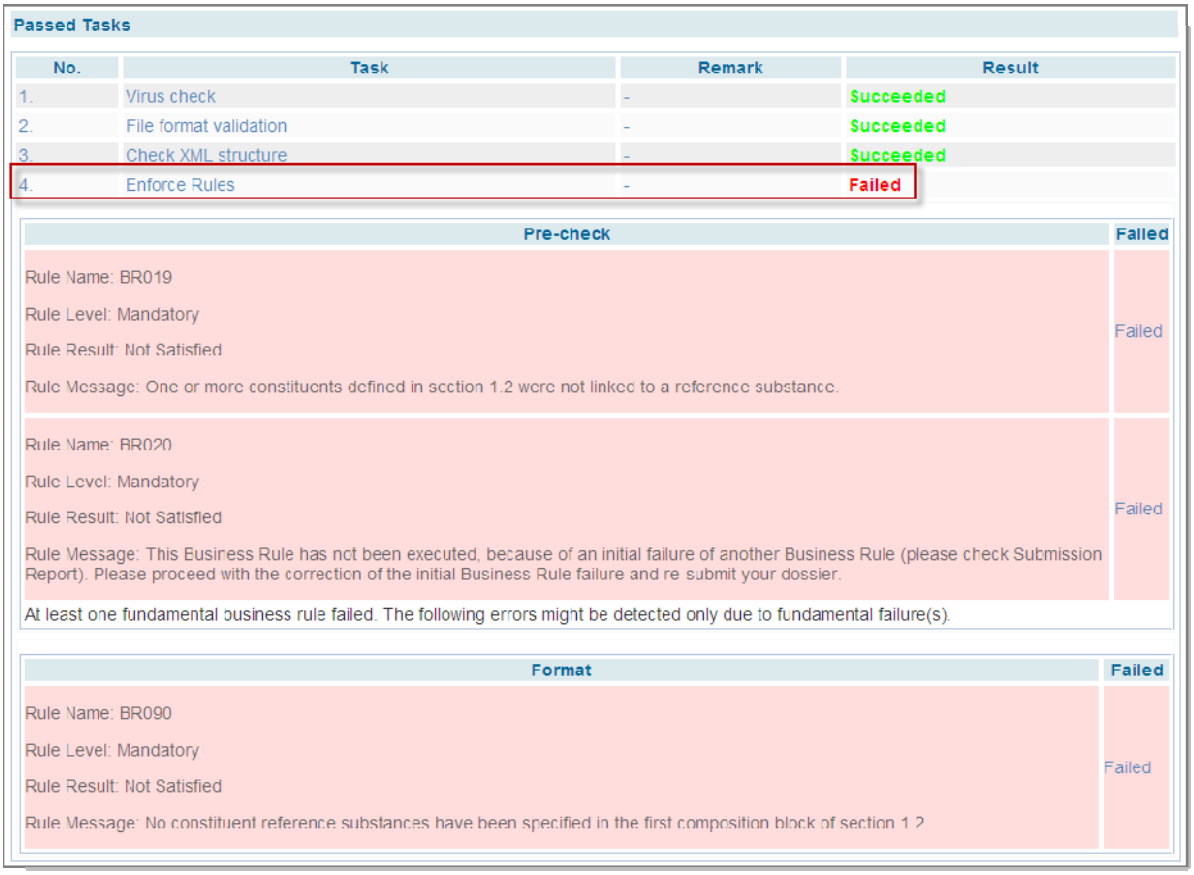


Figure 53 provides an example of how the information on the automated business rules is displayed in the submission report.

Figure 53: Submission report



For each failed automated business rule, the <Submission report> gives the reason of failure as indicated in
Figure 54.

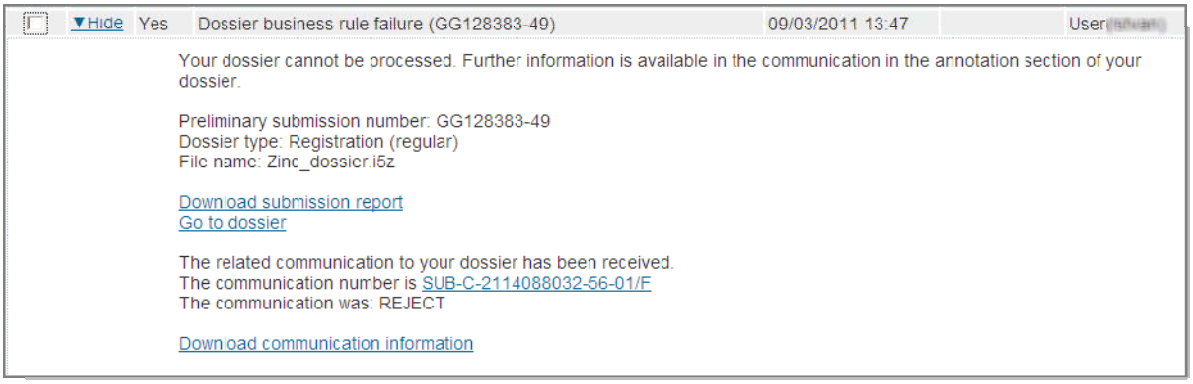
Figure 54: Submission report with details

Rule Name: BR019
Name of the failing mandatory Business Rule
Rule Level: Mandatory
Rule Result: Not Satisfied
Reason of failure
Rule Message: One or more constituents defined in section 1.2 were not linked to a reference substance.
Failed

What happens when a dossier fails a manually checked business rule?

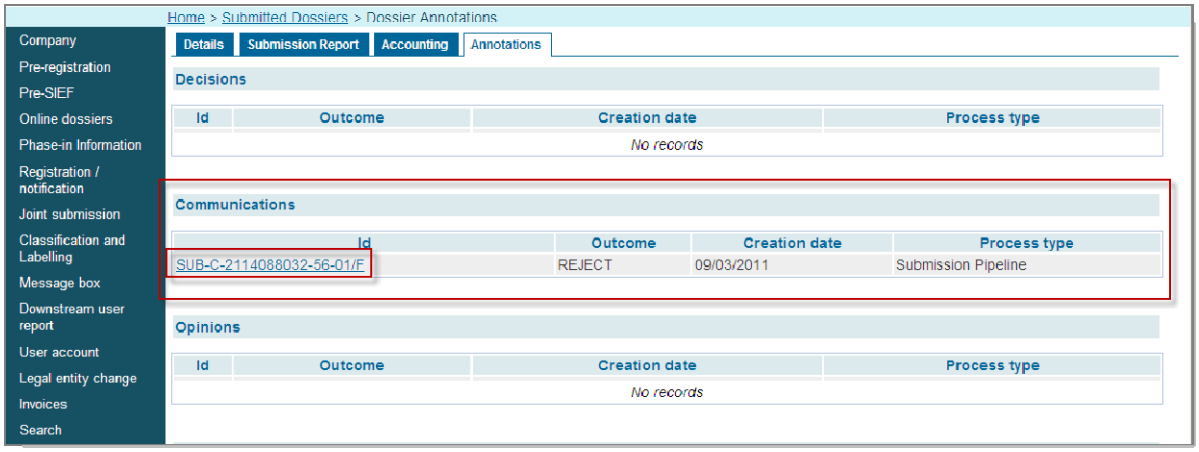
If the submitted dossier cannot be processed due to one or more manually checked business rules, ECHA sends a message to the registrant's/notifier's REACH-IT mailbox. This message entitled <Dossier business rule failure> is displayed in Figure 55.

Figure 55: REACH-IT message on BR failure – manual check


▼Hide
Yes
Dossier business rule failure (GG128383-49)
09/03/2011 13:47
User
Your dossier cannot be processed. Further information is available in the communication in the annotation section of your dossier.
Preliminary submission number: GG128383-49
Dossier type: Registration (regular)
File name: Zinc_dossier.i5z
Download submission report
Go to dossier
The related communication to your dossier has been received.
The communication number is SUB-C-2114088032-56-01/F
The communication was: REJECT
Download communication information

As stated in the message, further information is available in the <Annotation> tab under <Communications> in the dossier. The easiest way to access that information is clicking the <Go to dossier> link, and then click the <Annotations> tab (see Figure 56).

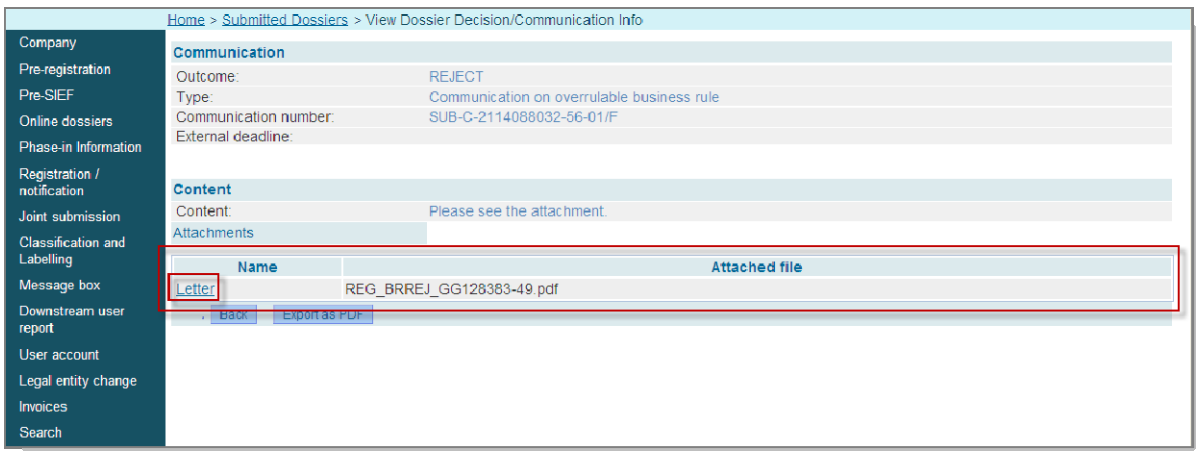
Figure 56: Annotations tab with Communications



Clicking the link of the <Communication number> (the one in the inner red box in the above screenshot) you will be able to open the attachment (a PDF document, see Figure 57) containing:

- all details on the failure
- the actions you should take to submit a valid dossier.

Figure 57: Attached communication in the dossier info



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